



Original Article:

Over the counter ophthalmic drug misuse, are we aware?

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Abstract:

Aim: To investigate the misuse of 'over the counter' ophthalmic medications in our city. **Method:** Responses of a structured questionnaire covering various aspects of over the counter drug use was obtained from pharmacy workers in and around our city. **Results:** Eighty nine pharmacy workers took part in this cross-sectional study. An average number of seven patients per day with ophthalmic complaints were seen by the pharmacy workers. Dispensing over the counter was practiced by 89.9% of the pharmacists. The most common complaint of the patients visiting the pharmacy, was redness and itching (86.5%). Antibiotics (96.6%) were the most common eye drops dispensed over the counter, followed by steroids (55.1%), decongestants (54.1%), antibiotic-steroid combination eye drops (29.2%) and lubricants (16.8%). Awareness regarding complications of steroid use was seen in 40.6% of pharmacists. 6.7% pharmacists had seen patients with complications following use of over the counter medications. In our study, majority of the eye drops dispensed were prescription drugs. **Conclusion:** Availability of prescription eye drops over the counter is an immense public threat. Educating the pharmacist and the population can decrease ocular morbidity. Research into methods to effectively deal with over-the-counter drug misuse is required and law can be enforced based on the findings.

Key Words: Over the counter, drug misuse, eye drops, pharmacy, non-prescription drugs

Introduction:

'Over the counter' (OTC) drugs are those which are legally permitted to be sold by a pharmacist without the prescription of a Registered Medical Practitioner. In the Indian context, the phrase 'over the counter' and the abbreviation OTC are not commonly used and the medicines are referred to as non prescription drugs.¹

The term 'over the counter' does not have much significance in India since many of the drugs are available without prescription on demand by patients at the pharmacy. Even though there are many laws and regulations prohibiting the practice of dispensing of prescription drugs without prescription, the practice is rampant. Almost every prescription drug is available without a doctor's prescription all over the country. In In-

dia, laws which regulate this are not as stringently imposed, as in other countries such as the United States.²

OTC use is a common patient self care practice.³ It is a matter of great concern when complications occur. Eye problems have increased due to this pharmacy related drug misuse. Pharmacy workers role in these types of eye problems will be assessed in our study.

The term OTC has been used in this article for both prescription and non prescription drugs which are dispensed by the pharmacy workers (includes pharmacists and other workers dispensing in pharmacy) without prescription.

Methods:

Pharmacy workers in an area covering roughly 60km radius around our city were included in this study. A questionnaire covering various aspects of OTC ophthalmic medication misuse, to be completed anonymously, was devised. A total of 117 pharmacy workers were approached to fill in the questionnaire and of these, 89 pharmacy workers agreed to participate in the study. Verbal informed consent was obtained from all the participants.

The questionnaire was as under:

- Average number of patients with eye complaints seen
- Common complaints of the patients (common complaints were listed in the questionnaire and the pharmacists were asked to tick)
- Common ophthalmic preparations dispensed
- Awareness of various ocular complications, such as, corneal problems, glaucoma, etc. following the use of steroid eye drops
- Any complications seen by the pharmacy workers following OTC dispensing.

An opinion regarding banning of OTC dispensing was also obtained. Responses were evaluated.

Results:

Eighty nine pharmacy workers took part in this cross-sectional study. Mean age of the pharmacy workers was 35.1 years (+/- 11.2). 55 (62%) were males and 49 (55%) were graduates. Average number of patients with eye problems seen by the phar-

macy workers per day was 7.7 (+/-4.3). Over the counter dispensing was practiced by 86 (96.6%) of the pharmacy workers.

Table 1 shows the various ocular complaints of the patients. Redness and itching were the most common complaints encountered.

Complaints	Frequency	Percent
Redness	77	86.5
Itching	77	86.5
Pain	58	65.2
Watering	41	46.1
Foreign body sensation	16	18
Trauma	13	14.6

Table 2 shows the various drugs dispensed OTC by the pharmacy workers. Antibiotic eye drops were commonly dispensed. Steroid eye preparations, which come in the category of prescription eye drops, were dispensed by 55.1% of the pharmacy workers.

Eye drops	Frequency	Percent
Antibiotics	86	96.6
Steroids	49	55.1
Antibiotic and steroid combination	26	29.2
Decongestants	58	65.1
Lubricants	15	16.8

Eighty two (92.1%) of pharmacy workers advised the patients obtaining drugs over the counter to consult an ophthalmologist. Awareness of the complication of steroid use was seen in only 36 (40.6%) of the pharmacy workers. Six (6.7%) had seen patients with complications following the use of drugs over the counter. Pharmacy workers refused to reveal the complications. Thirty eight (42.7%) pharmacy workers opined positively regarding banning of OTC dispensing of ocular medications.

Discussion:

Ocular morbidity, following the use of OTC medications is discussed in this study. Although we could not gather information on what drugs were prescribed for a particular condition, the available data reveals flagrant misuse of ophthalmic preparations by pharmacy workers.

Decongestants, antihistamines and lubricants are the eye drops which have been approved for OTC use. Recently chloramphenicol eye drops too have been approved for over the counter use.⁴ The other available ocular medications are prescription eye drops.⁵

Antibiotics have been used by the patients for the mildest form of ocular problems. These eye drops when used for a long time result in both conjunctival and corneal toxicity.⁶ Sosa and coworkers⁶ studied the effect of Ofloxacin, Moxifloxacin, Gatifloxacin, Levofloxacin, Ciprofloxacin and normal saline on immortalized conjunctival and human corneal epithelial cells. All ophthalmic preparations showed both corneal and conjunctival cell toxicity. Normal saline showed the lowest amount of toxicity. Of the topical ocular antibiotics tested, Moxifloxacin showed the least amount of toxicity. All of the other antibiotics tested were statistically indistinguishable from each other from the toxicity point of view.

Delay in the actual ophthalmic expert treatment obtained by the red eye patients (Table 3)⁷ when treated by the pharmacy workers with antibiotic eye drops can give rise to severe ocular complications. These patients can turn out to be suffering

from uveitis, keratitis or acute angle closure glaucoma, which requires immediate treatment.

Conjunctival disorders and episcleritis	
•	Allergic or seasonal conjunctivitis
•	Chemical (irritant) conjunctivitis
•	Episcleritis
•	Infectious conjunctivitis
•	Subconjunctival hemorrhage
•	Vernal conjunctivitis
Corneal disorders	
•	Contact lens keratitis
•	Corneal abrasion or foreign body
•	Corneal ulcer
•	Viral keratitis
Other disorders	
•	Acute angle closure glaucoma
•	Acute uveitis
•	Scleritis

OTC ophthalmic decongestants are commonly used to control the discomfort in the eyes and ocular redness. In a study done by Tayanithi and coworkers⁸ on self medication with OTC ophthalmic solutions, the factor that most influenced the use of solutions was dust in the eye (55%). Ocular allergic symptoms, such as eye itching, irritation and tearing, were the second most common cause. Itching was the most common complaint in our study. Antihistamines and decongestants are commonly used to relieve the redness, but when steroids are used it can cause problems. Since these patients are relieved of their itching symptoms by the steroids obtained from the pharmacists, they fail to consult an ophthalmologist. These patients may end up with steroid induced glaucoma.⁹ OTC sale of topical steroids has been documented to lead to loss of vision, secondary to glaucoma.¹⁰

Topically used steroids can trigger attacks of herpetic keratitis. Hence the common practice of using a steroid preparation indiscriminately, for every type of external inflammation of the eye should be avoided.¹¹ Administration of corticosteroid eye drops in herpetic diseases of the eye can result in severe exacerbation of the disease, with the development of geographic or amoeboid ulcers and an increase in the incidence of subsequent complications.¹¹ In our study, steroids were dispensed by 55.1% of the pharmacists, a worryingly high figure.

Decongestants can result in acute and chronic forms of conjunctivitis by pharmacological, toxic, and allergic mechanisms.^{12,13} Soparkar and coworkers¹² in their study, describe the different patterns of conjunctivitis caused by ophthalmic decongestants. In their study, decongestants were used daily for a median period of 3 years (Range 8 hours to 20 years). Clinical patterns of conjunctivitis observed were- conjunctival hyperemia, follicular conjunctivitis and eczematoid blepharconjunctivitis.

Blindness from misuse of OTC eye drop preparations is also reported.¹⁴ The active ingredient in most of the ophthalmic decongestants is an alpha adrenergic receptor stimulator. Rumelt MB¹⁴ reported blinding of four eyes in three patients who used OTC preparations when they suffered angle-closure glaucoma. These drugs may augment existing mydriasis or precipitate it if used in excessive amounts. However it is not possible to estimate the number of cases of blindness from misuse of OTC eye drops.

OTC lubricants when used over the long term can produce corneal epithelial toxicity due to the preservatives present.¹⁵

The preservatives polysorbate and benzalkonium are highly cytotoxic as compared to chlorbutanol.¹⁶ Cytotoxicity decreases in the absence of preservatives.¹⁶ However preservative-free artificial tears are also not safe. These drops in re-useable containers are at risk of contamination in a daily and multiple use setting, especially in patients with a poor administering technique, which is associated with fingertip touch and advanced age.¹⁷ More studies are required to determine the most suitable lubricant for over the counter use.

Important ocular findings such as corneal abrasions, uveitis and retinal detachment following trauma can be totally missed when the patient is treated by pharmacy workers. Self prescription by the consumers who do not have medical knowledge carries the risk of gross errors of diagnosis and serious health consequences.

There are several study weaknesses that should be noted. First, fear of disclosing the ophthalmic preparations dispensed OTC may be the primary factor for false reporting. Second, laziness of the pharmacy workers to fill the questionnaire could give us a wrong data. Third, all the drugs dispensed and the number of patients visiting the pharmacy may not be documented accurately due to the loss of past memory of the pharmacy workers. Fourth, difference in reporting could be due to the random selection of pharmacies. More number of patients visit city pharmacies rather than rural pharmacies because of the difference in the density of population and easy access to the pharmacy in the city.

The Pharmacy act of 1948 regulates pharmacy practices in India.¹⁸ Pharmacists are expected to be careful and cautious while dispensing medicines to consumers. They are expected to educate the customers about intake and effects of drugs. Unfortunately in India some chemists are themselves not knowledgeable enough to educate consumers about OTC drugs. They neither insist on a prescription for a prescription drug nor question the customer about the need of a particular drug.¹⁹

Easy availability of a wide range of prescription drugs without prescription, low medical literacy among the population, advertising and also a desire to reduce the cost of health care seem to be the motivating factors for self medication. Development in self medication has to be carefully managed if the benefits are to be maximized and the potential risks kept to a minimum.

Doctors and the pharmacist play a very important role in creating awareness about self medication. Doctors can curb the use of unethical and irrational drugs by educating patients.

More studies are required in this field to know the severity of the situation. Current methods for dealing with abuse / misuse of OTC drugs are inadequate. Our government needs to take an initiative to curb this menace.

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