

ORIGINAL ARTICLE

Efficacy and safety of Olopatadine versus Azelastine in allergic conjunctivitis at a Government Medical College, Betiah, Bihar- A prospective study

Shawana Barkat, Anil Sinha

¹Senior Resident, ²Professor, Department of Pharmacology, Government Medical College, Betiah, Bihar, India


ABSTRACT:

Background: Allergic eye diseases influences around one-fifth of the total populace. Olopatadine hydrochloride and Azelastine hydrochloride are double acting selective H1 receptor antagonist with mast-cell stabilizing property. This investigation was embraced to evaluate the adequacy and wellbeing of olopatadine hydrochloride 0.1% and Azelastine hydrochloride 0.05% in allergic conjunctivitis. **Materials and Methods:** 80 patients with the sign (hyperemia) and side effects of allergic conjunctivitis (i.e., tearing, itching and photophobia) were randomized (stratifying by age and sex) 1:1 to get either 0.1% with olopatadine hydrochloride (OHCL) and Azelastine 0.05% eye drops BD for 15 days (one drop in each eye each 12 h). Signs and manifestations were scored prior and then afterward 2 weeks of medication while side effects were scored 30 min and 2 weeks after treatment start. A composite score of signs and indications was characterized by including all measures of signs and manifestations and after that subtracting the week 2 entirety from the pretreatment aggregate. **Result:** Both medications decreased signs and indications of allergic conjunctivitis at 2 weeks from gauge. The treatment with 0.1% OHCL was more powerful contrasted with the azelastine gathering. Essentially, the scores of ocular congestion, foreign body sensation, tearing, erythema and chemosis likewise demonstrated bigger decrease in the olopatadine treated patients. **Conclusion:** The aftereffects of this single-dosage contemplate recommend that olopatadine is better than epinastine regarding smothering ocular itching and hyperemia. Additionally contemplates are expected to affirm these discoveries, in real-life settings.

Keywords: Olopatadine hydrochloride(OHCL), Allergic conjunctivitis (AC), Hyperaemia.

Corresponding author: Dr. Anil Sinha, Professor, Department of Pharmacology, Government Medical College, Betiah, Bihar, India

This article may be cited as: Barkat S, Sinha A. Efficacy and safety of Olopatadine versus Azelastine in allergic conjunctivitis at a Government Medical College, Betiah, Bihar- A prospective study. J Adv Med Dent Scie Res 2017;5(8):47-51.

Access this article online	
Quick Response Code 	Website: www.jamdsr.com
	DOI: 10.21276/jamdsr.2017.5.8.2

Introduction: Allergic conjunctivitis (AC) is inflammation of the conjunctiva (the film covering the white piece of the eye) because of sensitivity. Seasonal hypersensitive conjunctivitis (SAC) and perennial susceptible conjunctivitis (PAC) are the most well-known types of unfavorably susceptible conjunctivitis and are caused by an IgE-intervened response to allergens, for example, grass, weed and tree dusts, clean parasites, creature dander and molds. Signs and side effects of Allergic conjunctivitis incorporate visual tingling, visual redness, tearing, eyelid swelling and chemosis.¹ The manifestations are because of arrival of histamine and other dynamic substances by mast cells, which animate secretion of veins, bother nerve endings, and increment discharge of tears. Treatment of

hypersensitive conjunctivitis is by staying away from the allergen (e.g., maintaining a strategic distance from grass in blossom amid "roughage fever season") and treatment with antihistamines, either topical (as eye drops), or fundamental (as tablets).²

Mast cells assume a critical part in the pathogenesis of AC. Authoritative of particular antigens on mast cells in the conjunctiva prompts mast cell degranulation and the arrival of histamine and other hypersensitive and inflammatory mediators.³ Histamine is the important go between, which is in charge of the real signs and side effects of AC including visual tingling, redness, tearing and top swelling in visual hypersensitivity. In the event that mast cell movement is not

blocked, manifestations, for example, tingling and red eye will proceed.⁴

Olopatadine is a anti-allergic agent that exerts its effects through multiple different mechanisms of action, including selective antagonism histamine H1 receptors, mast cell stabilization, and anticipation of histamine initiated inflammatory cytokine creation by human conjunctival epithelial cells. Olopatadine is utilized as a part of a few remedy items around the globe as a topical visual eye drop, a topical nasal spray and as an oral medicine. H1 selectivity of olopatadine is better than that of other visual antihistamines. Olopatadine hydrochloride 0.1% has a quick beginning of activity and has solid, particular antihistaminic and mast cell settling activity. It is extremely well endured when instilled furnishing patients with fast, powerful and durable alleviation from the signs and side effects of hypersensitive conjunctivitis.⁵

Presently a day's treatment for allergic conjunctivitis has particularly extended, giving more chances to pick a treatment however regularly leaving doctors confounded over the assortment of alternatives. Data is restricted about clinical result of patients with Allergic Conjunctivitis in our prospect. Part of works have been finished with olopatadine abroad, however so far we know there was no examination done in our nation in regards to the impact of as of late accessible medications olopatadine on eye.⁶ Olopatadine hydrochloride 0.1% is one such single atom with double properties restraining immediate hypersensitivity reactions and providing long term membrane stabilization.⁸ Azelastine, with comparative properties, gives quick help and the early-stage intercession represses expression and activation of inflammatory mediators which characterize the late phase of the immune reaction.^{7,8} Both have been accounted for to be viable and very much endured in the treatment of unfavorably susceptible conjunctivitis however the constrained collection of confirmation incited us to assess the adequacy and wellbeing of these two visual arrangements. The goal of this examination was to compare the reduction in the ocular signs and symptoms scores, safety and tolerability of olopatadine hydrochloride 0.1% eye drops versus Azelastine 0.05% eye drops in the treatment of allergic conjunctivitis in patients at government medical college, Betiah, Bihar.

Materials and Methods:

This prospective interventional study was carried out in the Department of Ophthalmology at Government Medical College, Betiah, Bihar. We analyzed AC and chose patients in light of the clinical sign (hyperemia) and side effects (tearing, visual itching and photophobia). A clinical analysis of AC was made in light of the strange clinical indication of

hyperemia on slit light examination. No different techniques for finding were considered other than clinical signs and manifestations. The patients who went to the ophthalmology OPD with the conclusion of allergic conjunctivitis were taken as the investigation subjects, according to incorporation criteria-an unfavorably susceptible conjunctivitis persistent with hyperaemia, tearing, visual itching and photophobia and rejection criteria-related with other foundational or visual sickness (bronchial asthma), skin inflammation, dry eye, uveitis, infective conjunctivitis, accepting fundamental or topical visual medicine, pregnancy and so on.

The targets, nature, reason and potential hazard and advantages of all strategies utilized for the examination were disclosed in detail to the patients and educated composed assent was taken before randomization. Point by point history and clinical examination were performed in an endorsed information accumulation frame

In the wake of satisfying the choice criteria, 80 patients who qualified, incorporated into the investigation, were chosen arbitrarily as each patient with even enlisted number got Olopatadine hydrochloride 0.1% eye drops twelfth hourly and odd enrolled numbers got Azelastine 0.05% eye drops twelfth hourly for 15 days. Both investigation drugs were utilized at their promoted focuses. All investigation drugs were directed by a prepared doctor in a twofold visually impaired way. Scoring of hyperaemia, itching, tearing, and photophobia were recorded just previously, then after the fact 2 weeks of medication treatment.

At follow-up visit data on concomitant medications, ocular symptoms such as itching, foreign body sensation, stinging, photophobia, watering was graded by the patients on a severity scale of 0 to 4. Similarly, ocular signs such as congestion, erythema, chemosis was graded by ophthalmologist on a severity scale of 0 to 4.

During treatment the patients were told to answer to Ophthalmology OPD or to contact with the main specialist if any issue stirred, for example, foreign body sensation/stinging, migraine, sedation, dry eye, declining of side effects/non reaction to treatment and so forth. Every patient was assessed 30 min and 2 weeks after treatment start for adverse effects.

Result: Both medications decreased signs and indications of allergic conjunctivitis at 2 weeks from gauge. The treatment with 0.1% OHCL was more powerful contrasted with the azelastine gathering. Essentially, the scores of ocular congestion, foreign body sensation, itching, erythema and chemosis likewise demonstrated bigger decrease in the olopatadine treated patients.

Table 1: Demographic characteristics of subjects under study

Characteristic	Olopatadine group (n=40)	Azelastine group (n=40)
Age (years)	32.7± 4.3	33.82± 3.4
Gender		
Male	24	27
Female	16	13
Occupation		
Student	6	5
Indoor worker	2	3
Outdoor worker	11	9
Factory worker	18	21
Others	3	2
Smoking		
Yes	18	21
No	22	19
Type of allergen		
Ragweed	9	7
Dust mites	8	11
Grass	11	9
Trees	4	6
Animal dander	5	3
Parasites	3	4

Table 2: Mean scores of signs and symptoms in both groups

Signs and symptoms	Score in Olopatadine group		Score in Azelastine group	
	Before	After	Before	After
Hyperemia	3.5	0.2	3.5	1.6
Itching	3.7	0.3	3.8	1.4
Photophobia	3.1	0.1	3.4	2.0
Watering	2.9	0.0	3.2	1.8
Foreign body sensation	3.2	0.1	3.2	1.6
Chemosis	2.7	0.3	2.9	1.1
Congestion	2.5	0.7	3.0	1.0
Erythema	3.1	0.9	3.5	1.1

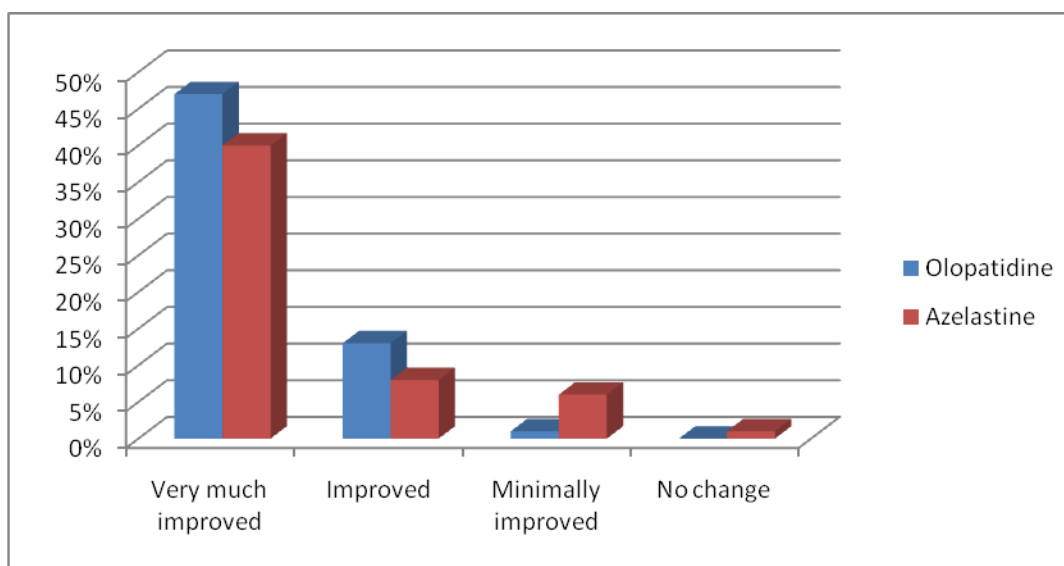


Figure 1: Improvement in both groups

Discussion:

Allergic eye disease is a typical issue in day by day rehearse which influences over 20% of the total populace and weakens their every day exercises; the quantities of casualties are expanding step by step alongside the ecological contamination and ophthalmologists are essentially confronting it day by day.⁹ Allergic conjunctivitis hampers personal satisfaction. The objective of treatment for regular allergic conjunctivitis is to viably resolve clinical signs and indications, and enhance personal satisfaction. The pharmacotherapy of allergic conjunctivitis comprises of a few classes of medications: antihistamines, mast cell stabilizers, double acting agents, NSAIDs and corticosteroids.

Allergic conjunctivitis hampers personal satisfaction as patients with AC much of the time give side effects of allergic rhinitis.¹⁰ In the present investigation the viability, security and fairness of two topical double acting against allergic medications, olopatadine and azelastine were contrasted in patients and hypersensitive conjunctivitis. Every one of the patients selected in the examination were incorporated for investigation as there were no drop outs. Non responders were regarded with extra drugs, for example, topical steroids and immunosuppressants. The objective of treatment for AC is to adequately resolve clinical signs and side effects and enhance personal satisfaction. We led a twofold covered randomized trial to see if OHCL is more compelling contrasted and Azelastine in the administration of AC. In this trial, information from 80 patients with AC going to the ophthalmology outpatient office were broke down. Out of 80 patients, 40 got Azelastine 0.05% and 40 got 0.1% OHCL. To enhance personal satisfaction it is essential to get early alleviation from signs and side effects of AC.^{11,12}

Our trial found that the general viability of 0.1% OHCL is measurably fundamentally higher than that of Azelastine 0.05% in lessening the sign and side effects of AC 2 weeks after establishment. In particular, huge adequacy was seen in diminishing the signs and side effects of hyperemia, tearing, itching and photophobia.¹³ This model is suitable to test the adequacy of anti-allergic agents, as it precisely recreates in a controlled and reproducible setting the genuine IgE-mediated allergic reaction found in patients with allergic conjunctivitis. As already said, the visual indications of rhinoconjunctivitis can influence the personal satisfaction of patients. Olopatadine satisfies the requirement for a treatment that gives full side effect help over the span of a whole 24-hour day. The present examination has demonstrated that olopatadine 0.1% is better than its vehicle for the treatment of visual tingling at the beginning of activity (quickly in the wake of dosing).¹⁴

Majority of the patients in this investigation had a place with the 26-40 years age gathering. This was predictable with the examinations done by John et al, and Abokyi et al,

where the mean period of hypersensitive conjunctivitis patients was around 30 years.^{15,16} An investigation done in Spain uncovered the both children and grown-ups were most usually influenced with allergic conjunctivitis.¹⁷ However, patients under 18 years were excluded in the present investigation.

Factory and outdoor workers are at an expanded danger of such allergic reactions.¹⁸ 48% and 20% of the investigation members were factory and outdoor workers individually. This reality is all around attested in a near report done in sawmill specialists which demonstrated that the occurrence of unfavorably susceptible conjunctivitis was more in the specialized laborers than the managerial workers.¹⁹ Allergic conjunctivitis is the most widely recognized ailment influenced by ecological varieties. Smoking influences the visual surface, which brings about side effects like irritation, redness and disturbance of eyes. The progressions on visual surface related with smoking incorporate change in lipid layer of tear film, diminished tear emission and diminished corneal and conjunctival sensitivity.²⁰

Olopatadine and azelastine, both adequately diminished the scores at the ensuing follow up visits yet the lessening in the olopatadine treated gathering was altogether bigger contrasted with patients treated with azelastine.²¹ The discoveries of this examination are reliable with the results noted in the two imminent investigations contrasting olopatadine and azelastine, the patient-detailed PACE contemplate and the specialist revealed CAC study.²²

The reasons why olopatadine indicated unrivaled adequacy (itching and redness relief) to Azelastine in this examination and prior investigations stay to be clarified. One conceivable clarification is that the two medications indicate diverse affinities for histamine receptors in the conjunctiva, vital focuses for treating unfavorably susceptible conjunctivitis and related hypersensitive visual illnesses.²³ Olopatadine was accounted for to have a mixed antagonistic profile (competitive and noncompetitive inhibition) against histamine H1 receptors, while Azelastine is a competitive inhibitor.²⁴ Likewise, olopatadine showed the best inhibitory impacts among the counter histamines tried in that review, acting in a focus subordinate way. Another probability is that olopatadine additionally has calming impacts, which incorporate concealment of interleukin (IL)- 6 and IL-8 creation by conjunctival epithelial cells, by restraining an assortment of histamine related signaling pathways.²⁵ Olopatadine likewise effects on mast cell adjustment than Azelastine.^{26,27}

A few impediments of this investigation are that the adequacy of the examination drugs was surveyed at a solitary visit. Also, on account of the approach utilized as a part of the present investigation, we couldn't look at the combined impacts of presentation to the allergen or the impacts of treatment for a few successive days or weeks, which may be required, all things considered, settings. It is likewise vital to consider that the outcomes may not have

any significant bearing to hypersensitive conjunctivitis caused by other basic allergens. At long last, recognize that the convergences of the olopatadine (0.1%) and Azelastine (0.05%) arrangements contrasted.

Conclusion:

0.1% OHCL is more viable and more secure (for the time being) than Azelastine 0.05% in the administration of AC. Patients treated with OHCL had a decent recuperation of visual hyperemia and indications ascribed to AC with no announced antagonistic occasions and subsequently this offers a promising new procedure for the administration of this ailment. Also, less incessant measurements with moderately minimal effort OHCL may prompt enhanced patient consistence. In clinical practice it might give a valuable treatment for AC patients who can't accomplish a palatable hostile to hypersensitive impact with other solution, for example, Azelastine.

References:

- Manzouri B, Flynn TH, Larkin F, Ono SJ, Wyse R. Pharmacotherapy of allergic eye disease. *Expert Opin. Pharmacother.* 7(9), 1191–1200 (2006).
- Bielory L. Current reviews of allergy and clinical immunology. *J. Allergy Clin. Immunol.* 106(6), 1019–1032 (2000).
- Singh K, Axelrod S, Bielory L. The epidemiology of ocular and nasal allergy in the United States, 1988–1994. *J. Allergy Clin. Immunol.* 126, 778–783 (2010).
- Leonardi A, Zafirakis P. 2004, 'Efficacy and comfort of olopatadine versus ketotifen ophthalmic solutions: A double-masked, environmental study of patient preference', *Current Medical Research & Opinion*, 20: 1167-1173.
- McGill J. 2004, 'A review of the use of olopatadine in allergic conjunctivitis', *International Ophthalmology*, 25:171-179.
- Leonard B, Kenneth WL, Steve B. 2005, 'Efficacy and Tolerability of Newer Antihistamines in the Treatment of Allergic Conjunctivitis', *Drugs*; 65:215-228.
- Sharif NA, Xu SX, Miller ST, Gamache DA, Yanni JM. 1996, 'Characterization of the ocular antiallergic and antihistaminic effects of olopatadine (AL-4943A), a novel drug for treating ocular allergic diseases', *American Society for Pharmacology and Experimental Therapeutics*, 278:1252-1261
- Chigbu DI. The management of allergic eye diseases in primary eye care. *Cont Lens Anterior Eye.* 2009;32(6):260–272.
- Virchow JC, Kay S, Demoly P, Mullol J, Canonica W, Higgins V. Impact of ocular symptoms on quality of life (QoL), work productivity and resource utilisation in allergic rhinitis patients – an observational, cross sectional study in four countries in Europe. *J Med Econ.* 2011;14(3):305–314.
- Blaiss MS. Allergic rhinoconjunctivitis: burden of disease. *Allergy Asthma Proc.* 2007;28(4):393–397.
- Uchio E. Treatment of allergic conjunctivitis with olopatadine hydrochloride eye drops. *Clin Ophthalmol.* 2008;2(3):525–531.
- Azari AA, Barney NP. Conjunctivitis: a systematic review of diagnosis and treatment. *JAMA.* 2013;310(16):1721–1729.
- Uchio E. Treatment of allergic conjunctivitis with olopatadine hydrochloride eye drops. *Clin Ophthalmol.* 2008;2(3):525–531.
- Yanni JM, Weimer LK, Sharif NA, Xu SX, Gamache DA, Spellman JM. Inhibition of histamine-induced human conjunctival epithelial cell responses by ocular allergy drugs. *Arch Ophthalmol.* 1999;117(5):643–647.
- John J, Ahmed S, Anjum F, Kebab M, Mohammed N, Darwich H. Prevalence of Allergies among University Students: A Study from Ajman, United Arab Emirates. *ISRN Allergy.* 2014:502052.
- Abokyi S, Koffuor G, Ntodie M, Kyei S, Gyanfosu L. Epidemiological profile and pharmacological management of allergic conjunctivitis: A study in Ghana. *Int J Pharm.* 2012;3(4):195-201.
- Peate WF. Work-Related Eye Injuries and Illnesses. *Am Fam Physician* 2007;75:1017-22.
- Njinaka I, Uhumwangho M, Edema TO, Dawodu OA, Omoti AE. A Comparison Study of Conjunctiva Disorders in Technical and Administrative Sawmill Workers in Nigeria. *Malaysian J Med Sci.* 2011;18(3):43-8
- Lois N, Abdelkader E, Reglitz K, Garden C, Ayres J G. Environmental tobacco smoke exposure and eye disease. *Br J Ophthalmol.* 2008;92(10):1304-10.
- Shubhrica. Effect of Environment on Eyes: A Review. *Indian Journal of Clinical Practice.* Sept 2013;24(4):381-4.
- Epstein AB, Hoven TV, Kaufman A, Carr W. Management of allergic conjunctivitis: an evaluation of the perceived comfort and therapeutic efficacy of olopatadine 0.2% and azelastine 0.05% from two prospective studies. *Clin Ophthalmol.* 2009;3:329-36.
- Spangler DL, Bensch G, Berdy GJ. Evaluation of the efficacy of olopatadine hydrochloride 0.1% ophthalmic solution and azelastine hydrochloride 0.05% ophthalmic solution in the conjunctival allergen challenge model. *Clin Ther.* 2001 Aug;23(8):1272-80.
- Bielory L, Ghafoor S. Histamine receptors and the conjunctiva. *Curr Opin Allergy Clin Immunol.* 2005;5:437–40.
- Matsumoto Y, Funahashi J, Mori K, Hayashi K, Yano H. The noncompetitive antagonism of histamine H1 receptors expressed in Chinese hamster ovary cells by olopatadine hydrochloride: its potency and molecular mechanism. *Pharmacology.* 2008;81:266–74.
- Matsubara M, Tamura T, Ohmori K, Hasegawa K. Histamine H1 receptor antagonist blocks histamine-induced proinflammatory cytokine production through inhibition of Ca²⁺-dependent protein kinase C, Raf/MEK/ERK and IKK/I kappa B/NF-kappa B signal cascades. *Biochem Pharmacol.* 2005;69:433–49.
- Yanni JM, Stephens DJ, Miller ST, et al. The in vitro and in vivo ocular pharmacology of olopatadine (AL-4943A), an effective anti-allergic/ antihistaminic agent. *J Ocul Pharmacol Ther.* 1996;12:389–400
- Yanni JM, Weimer LK, Sharif NA, Xu SX, Gamache DA, Spellman JM. Inhibition of histamine-induced human conjunctival epithelial cell responses by ocular allergy drugs. *Arch Ophthalmol.* 1999;117:643–7.

Source of support: Nil

Conflict of interest: None declared

This work is licensed under CC BY: *Creative Commons Attribution 3.0 License.*