

# Comparison of efficacy of olopatadine hydrochloride 0.1% and azelastine hydrochloride 0.05% eye drops for treatment of allergic conjunctivitis in rural South India

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## Abstract

**Introduction:** Conjunctival inflammation due to allergy is known as allergic conjunctivitis. Common ocular symptoms may be itching, swelling of eyelids, watering, watery discharge, photophobia and foreign body sensation.

**Aims and Objectives:** To Compare the efficacy of Olopatadine Hydrochloride 0.1% and Azelastine Hydrochloride 0.05% Eye drops for Treatment of Allergic Conjunctivitis in Rural South India.

**Methodology:** A prospective clinical trial in 74 patients was carried out. Patients by random selection were given treatment by Olopatadine Hydrochloride 0.1% and Azelastine Hydrochloride 0.05% eye drops. Patients were assessed by ophthalmologist 0, 3<sup>rd</sup>, 7<sup>th</sup> and 14<sup>th</sup> day after starting treatment. During visits the symptom were graded from zero to three scale.

**Result:** The mean age in Olopatadine group was 18± 3.6 years and in Azelastine group was 19± 4.4 years. There were 26 Males and 11 Females in Olopatadine group and 28 Males and 9 Females in Azelastine group. The mean values for the duration of disease in both the groups were 2.8± 2.2 months and 2.9± 2.4 months respectively in Olopatadine and Azelastine group. The symptoms were compared in the two groups on 3<sup>rd</sup>, 7<sup>th</sup> and 14<sup>th</sup> day after starting treatment. The score given by the Ophthalmologist were markedly lower in both groups after treatment during all visits. (P<0.05).

**Conclusion:** Both Olopatadine and Azelastine reduced symptoms of allergic conjunctivitis very significantly however Olopatadine was more effective.

**Keywords:** Allergic Conjunctivitis, Olopatadine Hydrochloride, Azelastine Hydrochloride.

## Introduction

Conjunctival inflammation due to allergy is known as allergic conjunctivitis.<sup>(1)</sup> Common ocular symptoms may be itching, edema of eyelids, lacrimation, photophobia and sensation of foreign body in the eye.<sup>(1,2)</sup> The cause is interaction of our immune system and the allergen. It is seen more often when other allergic conditions are present for example eczema, asthma and hay fever.<sup>(4)</sup> Mast cells have important role in etiopathogenesis.<sup>(5)</sup> There are numerous allergens but the commonest cause is allergy to pollens. Others may be cosmetics, some medicines certain seeds and many others. This condition is more prevalent in warm season than cold. Most common form of allergic conjunctivitis is Seasonal Allergic Conjunctivitis (SAC). Such persons are often atopic and they have other allergic disorders. With usual symptoms of allergic conjunctivitis they may develop chemosis<sup>(6-8)</sup> Treatment may have a huge financial burden on the society costing millions of dollars and may affect quality of life.<sup>(9,10,11)</sup> Various treatment modalities are adopted for SAC such as topical decongestants, antihistaminic, mast cell stabilizers corticosteroids and lubricants. Immunotherapy and desensitization may be required<sup>(12-18)</sup>; treatment has to be tailor-made for individual patient. Some drugs are found to have dual action of antihistaminics and also mast cell stabilization: they are very useful in allergic conjunctivitis and being use extensively e.g. Topical Olopatadine and

Azelastine.<sup>(19)</sup> Ketotifen also possess multi-action like antihistaminic effect and inhibition of eosinophil.<sup>(20,21)</sup>

## Aims and Objectives

Comparison of efficacy of Olopatadine Hydrochloride 0.1% eye drops and Azelastine Hydrochloride 0.05% eye drops in Treatment of Allergic Conjunctivitis in Rural South India.

## Methodology

A prospective clinical trial in the 74 patients was done. Prior approval from Institutional Ethical Committee was obtained. Patients presenting with symptoms of allergic conjunctivitis were apprised of these two treatment modalities with their merits and demerits: consequently informed consent was taken before inclusion in the study. History of prior drug intake for allergic conjunctivitis was taken and if found positive it made exclusion of the patient. Patients were given treatment by Olopatadine Hydrochloride (0.1%) and Azelastine (0.5%) topical drops by random numbers assigned by computer. Patients were assessed by ophthalmologist 0, 3<sup>rd</sup>, 7<sup>th</sup> and 14<sup>th</sup> day after starting treatment. During visits the symptom were graded from zero to three scale. The 1-3 scale meant the presence of no symptom, mild, moderate and severe symptoms respectively. Similar grades are described in other studies too.<sup>(22)</sup>

**Result**

**Table1: Demographic Distribution of the Patients**

	<b>Olopatadine</b>	<b>Azelastine</b>
<b>Age (Mean±sd)</b>	18± 3.6 Yrs.	19± 4.4 Yrs.
<b>Sex</b>		
Male	26	28
Female	11	9
<b>Duration of Disease (Mean±sd)</b>	2.8± 2.2 Months	2.9± 2.4Months

From Table 1 the mean age in Olopatadine group was 18± 3.6 Yrs. And in Azelastine group was 19± 4.4 Yrs. There were 26 Males and 11 Females in Olopatadine group and 28 Males and 9 Females in Azelastine group. Mean duration of Disease in both the groups were 2.8± 2.2 Months. And 2.9± 2.4 Months. Respectively in Olopatadine and Azelastine group where these criteria can be compared with each other.

**Table 2: Symptomatic distribution of patients**

<b>Symptoms</b>	<b>Drugs</b>	<b>Baseline (Mean±sd)</b>	<b>p-value</b>	<b>Day -3 (Mean±sd)</b>	<b>p-value</b>	<b>Day-7 (Mean±sd)</b>	<b>p-value</b>	<b>Day14 (Mean±sd)</b>	<b>p-value</b>
Ocular-itching	Olopatadine	2.1± 1.3	P<0.05	1.52±1.1	P<0.05	1.40±0.78	P<0.05	0.9± 0.2	P<0.05
	Azelastine	2.6±1.12		2.3 ± 1.2		2.0±0.82		2.1± 0.3	
Burning sensation	Olopatadine	2.0±1.2	P<0.05	1.22± 0.75	P<0.05	1.10±0.30	P<0.05	0.82±0.4	P<0.05
	Azelastine	2.4± 1.1		2.2±0.08		2.0± 0.62		1.4±0.58	
Discharge	Olopatadine	2.1 ± 1.5	P<0.05	1.02± 1.3	P<0.05	0.98± 0.13	P<0.05	0.85±0.2	P<0.05
	Azelastine	2.1±1.2		2.2± 1.2		2.00± 0.22		1.4± 0.34	
Photophobia	Olopatadine	1.7± 1.1	P<0.05	1.05±1.23	P<0.05	0.99± 0.12	P<0.05	0.64±0.12	P<0.05
	Azelastine	1.82±1.3		2.2± 1.12		2.1± 0.26		1.5± 0.25	
Foreign body sensation	Olopatadine	1.4± 1.5	P<0.05	1.1± 1.1	P<0.05	0.92±0.11	P<0.05	0.55±0.12	P<0.05
	Azelastine	1.8± 1.2		2.48± 2.1		2.34±0.21		1.22±1.2	
Swollen eye	Olopatadine	1.52± 0.8	P<0.05	1.34± 1.18	P<0.05	0.94±0.45	P<0.05	0.46±0.21	P<0.05
	Azelastine	1.24±0.86		1.89± 2.31		1.80±0.34		1.22±1.4	

All the symptoms mentioned in the column one of Table 2 were compared between the two groups on 3<sup>rd</sup>, 7<sup>th</sup> and 14<sup>th</sup> day. The score given by the Ophthalmologist were lower on both the groups on all occasions, however, they were more lowered on the Opopatadine group. (P<0.05; Unpaired t-test was used)

**Discussion**

National Health and Nutrition Examination Survey III (NHANES III) found that ocular symptoms, defined as “episodes of tearing and ocular itching”, affected 40% of the adult population in the United States, without appreciable age-wise difference.<sup>(23)</sup> In the months of May to August the presence of pollen and other aeroallergens like mites, animal epithelia etc. increases and it has been seen that the incidence of eye allergies also increases outnumber nasal allergies. Triggered more ocular symptoms than nasal manifestations. Various studies have shown positive relation of skin allergy tests and allergic conjunctivitis.<sup>(24,25)</sup> A study<sup>(26)</sup> revealed that 90% of all patients with seasonal allergy show allergy to pollens.

Various modes of treatment are available for the treatment of allergic conjunctivitis which includes: Topical and systemic antihistaminic, mast cell stabilizers, dual action antihistaminic having mast cell stabilizing action also, topical cyclosporine and the most effective topical steroids. Supportive treatment include artificial tears, mucolytic agents etc. Trials have been done to compare various medications in the treatment of allergic conjunctivitis. In one study topical olopatadine, emedastine, lotepred were compared and all were found better than placebo, however there was no statistical difference in the efficacy among themselves.<sup>(27)</sup>

Though steroids are the most effective agents, there side effects are well known which include: risk of development of cataract, glaucoma, delayed wound healing and increased chances of infection.<sup>(28)</sup> Medications having dual action of antihistaminics as well as mast cell stabilizer such as Olopatadine and Azelastine have been found very useful.

This study conducted by us has shown that both Olopatadine and Azelastine reduced the symptoms of allergic conjunctivitis to a large extent, however this aim was achieved better in the Olopatadine group. These findings are similar to that found in study done by Spangler DL et al.<sup>(22)</sup>

## Conclusion

Both Olopatadine and Azelastine reduce the symptoms of allergic conjunctivitis to a large extent, however this aim was achieved better in the Olopatadine group.

## References

- Chigbu DI. The pathophysiology of ocular allergy: A review. *Cont Lens Anterior Eye* 32:3–15; quiz 43–44, 2009. [PubMed]
- Bielory L, Meltzer EO, Nichols KK, et al. An algorithm for the management of allergic conjunctivitis. *Allergy Asthma Proc* 34:408–420, 2013. [PubMed]
- Allansmith M.R., Ross R.N. (1991). "Phlyctenular keratoconjunctivitis". In Tasman W., Jaeger E.A. *Duane's Clinical Ophthalmology* 1 (revised ed.). Philadelphia: Harper & Row. pp. 1–5.
- "Conjunctivitis (inflammation of the eye)". [netdoctor.co.uk](http://netdoctor.co.uk). Archived from the original on 15 April 2010. Retrieved 2010-04-06.
- Leonardi A. The central role of conjunctival mast cells in the pathogenesis of ocular allergy. *Curr Allergy Asthma Rep* 2:325–331, 2002. [PubMed]
- Alexander M, Berger W, Buchholz P. The reliability, validity, and preliminary responsiveness of the Eye Allergy Patient Impact Questionnaire (EAPIQ). *Health Qual Life Outcomes* 2005;3:67.
- Gelardi M, Leo ME, Quaranta VN, et al. Clinical characteristics associated with conjunctival inflammation in allergic rhinoconjunctivitis. *J Allergy Clin Immunol Pract* 3:387–391.e1, 2015. [PubMed]
- Bielory L, Friedlaender MH. Allergic conjunctivitis. *Immunol Allergy Clin North Am* 2008;28:43-58.
- Pitt AD, Smith AF, Lindsell L, et al. Economic and quality-of-life impact of seasonal allergic conjunctivitis in Oxfordshire. *Ophthalmic Epidemiol* 11:17–33, 2004. [PubMed]
- Smith AF, Pitt AD, Rodriguez AE, et al. The economic and quality of life impact of seasonal allergic conjunctivitis in a Spanish setting. *Ophthalmic Epidemiol* 12:233–242, 2005. [PubMed]
- Ray NF, Baraniuk JN, Thamer M. Direct expenditures for the treatment of allergic rhinoconjunctivitis in 1996, including the contributions of related airway illnesses. *J Allergy Clin Immunol* 1999;103:401-7.
- Calderon MA, Penagos M, Sheikh A, et al. Sublingual immunotherapy for allergic conjunctivitis: Cochrane systematic review and meta-analysis. *Clin Exp Allergy* 41:1263–1272, 2011. [PubMed]
- Bielory L. Ocular allergy guidelines: A practical treatment algorithm. *Drugs* 2002;62:1611-34.
- Lin SY, Erekosima N, Kim JM, et al. Sublingual immunotherapy for the treatment of allergic rhinoconjunctivitis and asthma: A systematic review. *JAMA* 309:1278–1288, 2013. [PubMed]
- El Hennawi M. A double blind placebo controlled group comparison study of ophthalmic sodium cromoglycate and nedocromil sodium in the treatment of vernal keratoconjunctivitis. *Br J Ophthalmol*. 1994;78:365.
- Tinkelman DG, Rupp G, Kaufman H, Pugely J, Schultz N. Doublemasked, paired-comparison clinical study of ketorolac tromethamine 0.5% ophthalmic solution compared with placebo eye drops in the treatment of seasonal allergic conjunctivitis. *Surv Ophthalmol* 1993;38(Suppl):133-40.
- Ballas Z, Blumenthal M, Tinkelman DG, Kriz R, Rupp G. Clinical evaluation of ketorolac tromethamine 0.5% ophthalmic solution for the treatment of seasonal allergic conjunctivitis. *Surv Ophthalmol* 1993;38(Suppl):141-8
- Blais MS, Dykewicz MS, Skoner DP, et al. Diagnosis and treatment of nasal and ocular allergies: The Allergies, Immunotherapy, and Rhinoconjunctivitis (AIRS) surveys. *Ann Allergy Asthma Immunol* 2014;112:322–328.e321, 2014. [PubMed]
- Joss J, Craig T. Seasonal allergic conjunctivitis. *Drugs Today (Barc)* 1998;34:259-65.
- Berdy GJ, Hedquest B. Ocular allergic disorders and dry eye disease. Associations, diagnostic dilemma and management. *Acta Ophthalmol Scand* 2000;78:32-7.
- Manzouri B, Thomas HF, Larkin F, Ono SJ, Wyser R. Pharmacotherapy allergic eye disease. *Expert Opin Pharmacother* 2006;79:1191-200.
- 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.
- Singh K, Bielory L, Hackensack NJ, Newark NJ: Epidemiology of ocular allergy symptoms in United States adults (1988-1994). *Ann Allergy Asthma Immunol*. 2007;98:34-A22.
- Bonini S. Allergic conjunctivitis: the forgotten disease. *Chem Immunol Allerg*. 2006;91:110-20.
- Singh K, Bielory L, Hackensack NJ, Newark NJ. Ocular allergy: a national epidemiologic study. *J Allergy Clin Immunol*. 2007;119(Suppl 1):S154.
- Takano Y, Narita S, Kobayashi K. Seasonal allergic rhinitis in Hakodate. *Nippon Ganka Gakkai Zasshi*. 2004;108:606-11.
- Liu RF, Wu XX, Wang X, Gao J, Zhou J, Zhao Q. Efficacy of olopatadine hydrochloride 0.1%, emedastine difumarate 0.05%, and loteprednol etabonate 0.5% for Chinese children with seasonal allergic conjunctivitis: a randomized vehicle-controlled study. *Int Forum Allergy Rhinol*. 2016 Nov 21. doi: 10.1002/alr.21882. [Epub ahead of print]
- Polansky JR. Side effects of topical therapy with anti-inflammatory steroids. *Curr Opin Ophthalmol* 1992;3:259-72.