A COMPARISON OF THE EFFICACY OF OLOPATADINE HYDROCHLORIDE 0.1% OPHTHALMIC SOLUTION AND SODIUM CHROMOGLYCATE OPHTHALMIC SOLUTION IN THE TREATMENT OF ALLERGIC CONJUNCTIVITIS

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Abstract:

Aim: *To find out an effective drug for the treatment of allergic conjunctivitis and to compare the efficacy of Sodium chromoglycate ophthalmic solution and Olopatadine Hydrochloride 0.1% ophthalmic solution in the treatment of allergic conjunctivitis.*

Materials and methods: *This randomized double blinded study was conducted in National Institute of Ophthalmology and Hospital, Sher-E-BangIa Nagar, Dhaka, from January, 2005 to May, 2009. 100 Patients with ocular allergies attending OPD of NIO&H were included. Each of the patient was randomly included in either of the following two groups by simple lottery method;* Group A: *50 Patients receiving olopatadine hydrochloride 0.1% eye drops and* Group B: *50 Patients receiving sodium chromoglycate 2% eye drops. Itching score, Redness score, Discharge score, Evaluator's score – baseline and after 21 days of treatment with olopatadine and sodium chromoglycate 2% ophthalmic solution were evaluated following Aguilar (2000). For the relieving of symptoms and signs olopatadine was found to be superior over sodium chromoglycate 2% but the difference was not statistically significant.*

Conclusion: *This clinical study concludes that the relieving of symptoms and signs olopatadine was found to be superior over sodium chromoglycate 2% but the difference was not statistically significant.*

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Introduction:

Allergic conjunctivitis is a bilateral ocular disorder often causing extreme discomfort and affecting all age groups. The allergic response is due to immunoglobulin E mediated immunological mechanism releasing chemical mediators (histamine, platelet activating factor) by mast cell degranulation.

Till to date, many anti-allergic drugs have been introduced. Which include topical artificial tears, mast cell stabilizers like sodium chromoglycate 2% eye drops , vasoconstrictors, NSAIDs, steroids etc. But no single drug is as much effective in reducing acute allergic symptoms and signs. Thus, a combination of drugs are often used with topical steroid being common. As the treatment is of longer duration ,the adverse effect of steroid is common. Recently a newer class of dual acting agents have been introduced. This drugs act by blocking the H_1 receptors as well as act as a mast cell stabilizer. The drugs are Olopatadine 0.1% ophthalmic solution and Ketotifen fumerate 0.025% ophthalmic solution[1,2,3,4].

This study was conducted to find out an effective drug for the treatment of allergic conjunctivitis and to compare Efficacy of olopatadine hydrochloride ophthalmic solution and sodium chromoglycate 2% eye drops in the treatment of allergic conjunctivitis

Materials and Methods:

This randomized double blinded study was conducted in National Institute of

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Ophthalmology and Hospital, Sher-E-BangIa Nagar, Dhaka-1207 from : January, 2005 to May, 2009. 100 Patient with ocular allergies attending OPD of National Institute of Ophthalmology and Hospital were included. Written informed concent was taken from each patients and a thorough ocular examination was done.

Each of the patient was randomly included in either of the following two groups by simple lottery method;

Group A: 50 Patients receiving olopatadine hydrochloride 0.1% eye drops.

Group B: 50 Patients receiving receiving sodium chromoglycate 2% eye drops.

Patients and evaluators were masked to the supplied drops. Drops were labeled as 'A' and 'B' after removing the commercial sticker. one group receives drug 'A' and the other group receives drug 'B'.

Demographic variables*:* Age, Sex, Type of allergic conjunctivitis

Outcome variables: Itching score, Redness score, Discharge score, Evaluator's score – baseline and after 21 days of treatment with olopatadine and receiving sodium chromoglycate 2% ophthalmic solution.

Symptom scoring protocol followed Aguilar, 2000 [5].

Observation and Results:

Fig – I shows age distribution of the study subjects. Of the 100 patients Minimum age was 11 years and maximum was 62 years with mean age 27.56 years ± 13.08 (SD).

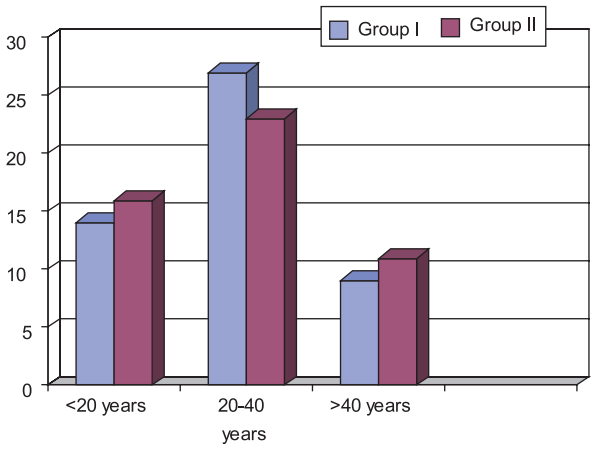

Table-I

Distribution of type of allergic conjunctivitis among the study subjects

Type of allergic conjunctivitis	Group A		Group B	
	No. of pts	%	No. of pts	%
Seasonal allergic conjunctivitis (SAC)	19	38	15	30
Vernal keratocon-conjunctivitis (SAC)	9	18	14	28
Atopic keratocon-junctivitis (AKC)	14	28	14	28
Giant papillary conjunctivitis	08	16	07	14

Table – II shows the distribution of mean itching score of the study subjects. Baseline mean itching score was 2.48 ± 0.55 (SD) in Group A and 2.36 ± 0.28 in Group B. Mean itching score after 07 days was 0.88 ± 0.42 in Group A and 1.04 ± 0.38 in Group B. Mean itching score after 21 days was 0.32 ± 0.44 in Group A and 0.52 ± 0.40 in Group B. Symptom relief was more in Group A cases but the differences was not statistically significant.

Table-II

Distribution of mean itching score of the study subjects

Period	Mean itching score ± SD		t/p value
	Group – A	*Group -B*	
Baseline period	2.48 ± 0.55	2.36 ± 0.28	0.47/0.51[ns]
After 07 days of treatment	0.88 ± 0.42	1.04 0.38	-0.96/0.10[ns]
After 21 days of treatment	0.32 ± 0.46	0.52 0.40	-1.5/.16 [ns]

P value reached from unpaired 't' test; ns = Not significant

Table – III : shows the distribution of mean redness score of the study subjects. Baseline mean redness score was 2.40 ± 0.39 (SD) in Group A and 2.46 ± 0.54 in Group B. Mean redness score after 07 days was 0.80 ± 0.40 in Group A and 0.90 ± 0.60 in Group B. Mean redness score after 21 days was 0.20 ± 0.31 in Group A and 0.36 ± 0.59 in Group B. Symptom relief was more in Group A cases but the differences was not statistically significant.

Table-III

Distribution of mean redness score of the study subjects

Period	Mean redness score ± SD		t / p value
	Group – A	*Group - B*	
Baseline period	2.40 ± 0.39	2.46 ± 0.54	-0.22/ 0.56[ns]
After 07 days of treatment	0.80 ± 0.40	0.90 0.60	-1.4/0.16 [ns]
After 21 days of treatment	0.20 ± 0.31	0.36 0.59	-1.8 / .18 [ns]

P value reached from unpaired 't' test; ns = Not significant

Similarly the distribution of mean discharge score of the study subjects - Baseline mean discharge score was 2.40 ± 0.69 (SD) in Group A and 2.46 ± 0.70 in Group B. Mean discharge score after 21days was 0.20 ± 0.40 in Group A and 0.30 ± 0.46 in Group B. Symptom relief was more in GroupA cases but the differences was not statistically significant.

Table – IV shows global assessment of efficacy of the study subjects. After 07 days' treatment 40 (80%) cases showed satisfactory improvement in Group A and 36 (72%) cases showed satisfactory improvement in Group B. After 21 days treatment 44 (88%) cases showed improvement in Group A and 40 (80%) cases showed improvement in Group B.

Table-IV

Distribution of global assessment of efficacy of the study subjects

Period	Group A No. of case (%)	Group B No. of case (%)	c^2 / p value
After 07 days:			
Satisfactoy -	40 (80)	36 (72%)	0.88/0.36 [ns]
Not satisfactory -	10 (20)	14 (28)	
After 21 days:			
Satisfactoy -	44 (88)	40 (80)	0.75/0.41[ns]
Not satisfactoy -	06 (12)	10(20)	

P value reached from Chi-squared test; ns = Not significant

Discussion:

This randomized double blind clinical trial was conducted in National Institute of Ophthalmology and Hospital.

100 patients with allergic conjunctivitis were randomly assigned in two groups to receive either olopatadine or sodium chromoglycate 2% eye drops.. Baseline mean itching score was 2.48 ± 0.55 (SD) in Group A and 2.36 ± 0.28 in Group B. Mean itching score after 07 days was 0.88 ± 0.42 in Group A and 1.04 ± 0.38 in Group B. Mean itching score after 21 days was 0.32 ± 0.44 in Group A and 0.52 ± 0.40 in Group B. Symptom relief was more in Group A cases but the differences was not statistically significant. Mean itching score was observed declining in the study of Aguilar (2000)[5]. Abelson *et al* (2004) [6,7]. Katelaris *et al* (2002)[8] showed mean itching score 1.93 after 15 days and 1.30 after 1 month in Olopatadine group. For sodium cromoglycate itching score was 2.03 after 15 days and 1.88 after 1 month. Olopatadine was found more potent in respect to mean itching score in those studies. The result of the current study is similar to that.

Redness score of the study shows that mean baseline redness score was 2.40 ± 0.39 (SD) in Group A and 2.46 ± 0.54 in Group B. Mean redness score after 07 days was 0.80 ± 0.40 in Group A and 0.90 ± 0.60 in Group B. Mean redness score after 21 days was 0.20 ± 0.31 in Group A and 0.36 ± 0.59 in Group B. Symptom relief was more in Group A cases but the differences was not statistically significant. Katelaris *et al* (2002)[8] showed that mean redness score after 15 days was 0.98 in Olopatadine group and 1.15 in sodium cromoglycate group; after 1 month mean redness score was 0.86 in Olopatadine group and 1.03 in sodium cromoglycate group. This result corresponds to that of the current study.

Mean discharge score was also found declining after treatment with both the drugs but more in Olopatadine group [9]. But the differences were not statistically significant.

After 07 days treatment 40 (80%) cases showed satisfactory improvement in Group A and 36 (72%) cases showed satisfactory improvement in Group B. After 21 days treatment 44 (88%) cases showed improvement in Group A and 40 (80%) cases showed improvement in Group B. Brutus *et al* (2000)[10] showed that global assessment of efficacy was more and quicker in Olopatadine group. James *et al* (2003) [11] found global assessment efficacy 81% for

Olopatadine and 66.3% for Cromolyn. These results correspond to the current study.

In our study the improvement rate was a bit higher as our study was conducted for 21days duration whereas the above mentioned studies were conducted for a period of 7 – 14 days.

This study was double masked and randomized clinical study. Patient's feeling regarding symptoms and comfort was taken into account and was assessed by a 4 point scale. Side by side, signs of allergic condition was assessed clinically and compared for the two anti-allergic ophthalmic preparations and marked as either 'satisfactory improvement' or not. For the relieving of symptoms Olopatadine was found to superior over sodium chromoglycate but the difference was not statistically significant. Clinical improvement rate was also higher in Olopatadine group.

Conclusion:

This double masked randomized clinical study done at NIOH concludes that both olopatadine and sodium chromoglycate 2% ophthalmic solutions are almost equally effective in reducing patients' symptoms and signs of allergic conjunctivitis. In a small number of patients olopatadine or sodium chromoglycate 2% alone is not as effective and require additional anti allergic drugs for clinical improvement. Further long-term multi-centered study is required for better evaluation.

References:

1. Lanny JR, O'Brien T, Weyne J. Mast Cell Stabilization and Anti-Histamine Effects of Olopatadine Ophthalmic Solution: a Review of Pre-Clinical and Clinical Research. Curr Med Res Opin. 2005 Aug; 20(5): 3064-3068.
2. Leonardi A. Role of histamine in allergic conjunctivitis. Acta Ophthalmol Scand 2000; 230(Suppl): 18–21.
3. Leonardi A: Emerging drugs for ocular allergy. Expert Opin Emerg Drugs 2005; 10(3): 505-520.
4. Ono SJ, Abelson MB: Allergic conjunctivitis: update on pathophysiology and prospects for future treatment. J Allergy Clin Immunol 2005 Jan; 115(1): 118-22.
5. Aguilar AJ. Comparative study of clinical efficacy and tolerance in seasonal allergic conjunctivitis management with 0.1% olopatadine hydrochloride versus 0.05% ketotifen fumarate. Acta Ophthalmol Scand Suppl 2000; 230: 52-55
6. Abelson MB, Gomes PJ, Vogelson CT, Pasquine TA, Gross RD, Turner FD, Wells DT, Bergamini MV, Robertson SM. Clinical efficacy of olopatadine hydrochloride ophthalmic solution 0.2% compared with placebo in patients with allergic conjunctivitis or rhinoconjunctivitis: a randomized, double-masked environmental study. Clinical Therapeutics. 2004; 26(8): 1237-1248.
7. Avunduk AM, Avunduk MC, Kapicioglu Z, Akyol N, Tavli L. Mechanisms and comparison of anti-allergic efficacy of topical lodoxamide and sodium chromoglycate treatment in vernal kerato-conjunctivitis. Ophthalmology. 2000 Jul; 107(7): 1333-7.
8. Katelaris CH, Ciprandi G, Missotten L, Turner FD, Bertin D, Berdeaux G; International Olopatadine Study Group. Comparison of the efficacy and tolerability of olopatadine hydrochloride 0.1% ophthalmic solution and sodium chromoglycate 2% ophthalmic solution in seasonal allergic conjunctivitis. Clin Ther. 2002; 24(10): 1561-1575.
9. Bielory L, Lien KW, Bigelsen S. Efficacy and tolerability of newer antihistamines in the treatment of allergic conjunctivitis. Drugs. 2005; 65(2): 215-228.
10. Butrus S, Greiner JV, Discepola M, Finegold I. Comparison of the clinical efficacy and comfort of olopatadine hydrochloride 0.1% ophthalmic solution and nedocromil sodium 2% ophthalmic solution in the human conjunctival allergen challenge model. Clin Ther. 2000; 22(12): 1462-1472.
11. James IG, Campbell LM, Harrison JM, Fell PJ, Ellers-Lenz B, Petzold U. Comparison of the efficacy and tolerability of topically administered azelastine, sodium cromoglycate and placebo in the treatment of seasonal allergic conjunctivitis and rhino-conjunctivitis. Curr Med Res Opin. 2003; 19(4): 313-20.