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# Demography, clinical profile and efficacy of dual action topical agents in patients of vernal keratoconjunctivitis from rural population of eastern Rajasthan state of India

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#### Abstract

**Purpose:** To study demographic and clinical profile of patients with vernal Keratoconjunctivitis (VKC) and to assess the efficacy and safety of treatment with topical agents having dual antihistaminic and mast cell stabilizing properties.

**Materials and Methods**: This is a prospective, observational study of 100 patients of VKC. All demographic data and clinical features of VKC was observed and recorded. Patients were treated with one of the two treatment options namely Bepotastine besilate 1.5% and Olopatadine hydrochloride ophthalmic solutions. Typical symptoms and signs of VKC namely ocular itching, watering, conjunctival hyperemia, tarsal papillary hyperplasia and limbal involvement including Horner Trantas dots were recorded at baseline and at time of follow up on 7<sup>th</sup> day, 15<sup>th</sup> and 30<sup>th</sup> day using simplified scoring. Safety assessment was also done.

**Results**: After 4 weeks of drug therapy, patients in both arms showed significant improvement in the symptoms and signs

**Conclusion**: VKC is a disease of younger population and having male preponderance. Both Bepotastine besilate 1.5% and Olopatadine hydrochloride 0.1% ophthalmic solutions were effective and safe in reducing the clinical symptoms and signs of VKC. However both the agents lacked efficacy in severe limbal forms of VKC.

**Keywords:** Vernal keratoconjunctivitis, Atopic keratoconjunctivitis, Perennial allergic conjunctivitis, Bepotastine besilate 1.5%, Olopatadine hydrochloride 0.1%

### Introduction

Allergic eye diseases comprises of conjunctivitis and occasionally keratitis in response to an allergen. These affect 10%-20% of people globally and have a negative impact on quality of life and productivity <sup>[1-6]</sup>. Allergic eye disease is classified into seasonal allergic conjunctivitis (SAC), perennial allergic conjunctivitis (PAC), vernal kerato-conjunctivitis (VKC), atopic kerato-conjunctivitis (AKC), contact blepharo-conjunctivitis, and giant papillary conjunctivitis <sup>[7-9]</sup>.

VKC is a chronic, recurrent bilateral inflammation of conjunctiva and cornea that has a tendency to occur in kids and young teenagers. It is usually a recurrent and seasonal allergic disease, but in severe cases, it turns into perennial. Presenting signs and symptoms include severe itching, swollen eyelid, tearing, red eye, foreign body sensation, mucus discharge, photophobia, lid edema, chemosis, tarsal papillae, Horner Trantas dots, limbal infiltrates (limbitis), giant papillae and corneal epitheliopathy [10,11].

The prevalence of vernal conjunctivitis was found to be 18% in a study done in Bangalore, India <sup>[26]</sup>. During the first decade of life around the age of 7 years, prevalence of VKC was found more in boys than girls. The male: female ratio was found to be is 2.3:1. The onset of the disease is around the age of 5 years and is usually resolved by puberty. Very rarely, the disease persists even after the age of 25 years.

Treatment of VKC is broadly divided into preventive, clinical and surgical options. Elimination and Avoidance of allergens like house dust mites and pollen are the preventive measures, while removing upper tarsal giant papillae or scraping fibrin from non-healing shield ulcers, constitute surgical options [14]. Other treatment options of VKC include topical mast cell stabilizers, anti-histaminics, corticosteroids, and immunomodulators [15].

Many studies have shown that olopatadine administered for the treatment of allergic conjunctivitis and VKC found to be effective, well tolerated, and safe. Olopatadine is now considered an established 1<sup>st</sup> line choice of treatment for patients of VKC along with topical steroids.

Olopatadine hydrochloride, a 2<sup>nd</sup> generation antihistamine, has both anticholinergic and mast cell stabilizer activity. It has histamine H1 receptor antagonism, chemical mediator suppression, tachykinin release inhibitory action and esosinophil infiltrative suppression actions [23, 24]. Olopatadine became approved for the treatment of seasonal allergic conjunctivitis and chronic allergic conjunctivitis in USA and the European Union, throughout 1996 and 2002, respectively. In case of severe allergic conjunctival diseases, olopatadine 0.1% drops is used once or twice daily regimen in the trade name of Pataday or Olopat, in India [25].

Bepotastine besilate is a 2<sup>nd</sup> generation non-sedating, selective antagonist of histamine (H1) receptor. Bepotastine besilate was approved for the treatment of allergic rhinitis and urticaria / pruritus in Japan. This ophthalmic solution is FDA approved since Sept 8, 2009 in the treatment of allergic conjunctivitis, with a Q12h in patients 2yrs of age and above. It has both selective histamine H1 receptor antagonism and mast cell stabilization actions [16-18].

Bepotastine, which is relatively a newer drug whose use in the treatment of VKC has been investigated in very few studies. Also, many comparative studies between gold standard drug olopatadine and bepotastine have been carried out for seasonal allergic conjunctivitis but very few for VKC.

# **Materials and Methods**

This was a Prospective Observational study conducted in Outpatient department of Ophthalmology, NIMS Hospital, Jaipur for 18 months after getting clearance from University Research Committee and Ethical Committee. Sample size calculation was done based on the sample size equation considering confidence interval 95% and error 5%

All the patients presenting to NIMS Ophthalmology OPD with signs and symptoms of ocular allergy underwent detailed history and examination on slit lamp. Those fulfilling the criteria had been enrolled in the study with written informed consent from patients or legal guardians of enrolled patients.

All the patients then underwent detailed history and ocular examination with symptoms and signs observed and recorded in the preformed and structured proforma including best corrected visual acuity (BCVA), slit lamp bio-microscopy and fundus examination. Objective symptoms such as itching, watering and signs such as conjunctival hyperaemia, tarsal papillae and Horner Trantas dots were observed and recorded in the preformed proforma on baseline 0 day (before treatment).

The study included 100 patients having VKC. The patients were treated with either Bepotastine besilate (1.5%) in both eyes (Group 1) or Olopatadine Hcl (0.1%) Group 2 in both eyes. Patients were re-examined on 7<sup>th</sup> day, 15<sup>th</sup> day, and 1 month after initiation of treatment. On each follow up detailed history and slit lamp examination were done and symptoms and signs were noted in the proforma as before and even side effects of both drugs applied were noted along with symptoms and signs. Severity of signs and symptoms were assessed on a pre determined 4- point scale where Grade 0 means no symptoms/signs, Grade 1 means mild symptoms/signs, Grade 2 means moderate symptoms/signs and Grade 3 means severe symptoms/signs [27].

#### **Inclusion criteria**

- 1) Patients of age group between 5-20 years coming to Ophthalmology OPD in NIMS Super Speciality hospital diagnosed with VKC.
- Patients who gave assent and whose legal guardians signed the voluntary informed consent.

# **Exclusion criteria**

- 1) One eyed patients.
- Patients with any other active ocular inflammatory conditions.
- 3) Patients with any contradictions or hypersensitivity to the use of the study medication or their components.
- 4) History of ocular trauma.
- 5) Patients having major toxicity to any of the above mentioned topical drops were withdrawn from study.

#### **Results and observations**

Table 1: Distribution of Study Population According to Age Groups

Age Groups	Group 1 (Bepotastine Besilate 1.5%)	Group 2 (Olopatadine HCl 0.1%)	Total
5-10 years	29	30	59
11-20 years	21	20	41
Total	50	50	100

29 patients of VKC in group 1 are less than 10yrs age group and 21 patients are in between 11-20yrs age group in the study population whereas 30 patients with VKC in group2

are less than 10yrs age group and 20 patients are in 11-20yrs age group.

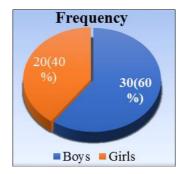


Fig 1: Distribution of Study Population According to Their Gender in Group 1

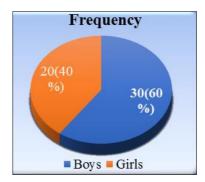


Fig 2: Distribution of Study Population According to their Gender in Group 2

Boys are 60% and Girls are 40% in group 1 and group 2 who are given Bepotastine besilate 1.5% and olopatadine Hcl 0.1% respectively for VKC treatment.

**Table 2:** Comparison of Group 1 and Group 2 with Itching on day 1, day 7, day 15 and at 1 month on treatment with Bepotastine besilate 1.5% & Olopatadine Hcl 0.1% respectively.

Itching				
Time	Grading	<b>Group 1 (Bepotastine Besilate 1.5%)</b>	Group 2 (Olopatadine HCl 0.1%)	P value
Day 1	1	25(50%)	25(50%)	
	2	20(40%)	20(40%)	0.112
	3	5(10%)	5(10%)	
Day 7	0	25(50%)	25(50%)	0.112
	1	20(40%)	20(40%)	
	2	5(10%)	5(10%)	
Day 15	0	45(90%)	45(90%)	0.422
	2	5(10%)	5(10%)	0.432
At 1 month	0	45(90%)	45(90%)	0.432
	1	5(10%)	5(10%)	0.432

Comparison of group 1 and group 2 on treatment for itching on day 1, day 7, day 15 and at 1 month is not statistically significant.

**Table 3:** Comparison of Group 1 and Group 2 with Tearing on day 1, day 7, day 15 and at 1 month on treatment with Bepotastine besilate 1.5% & Olopatadine Hcl 0.1% respectively.

Tearing				
Time	Grading	Group 1 (Bepotastine Besilate 1.5%)	Group 2 (Olopatadine HCl 0.1%)	P value
Day 1	1	25(50%)	25(50%)	
	2	20(40%)	20(40%)	0.112
	3	5(10%)	5(10%)	
Day 7	0	35(70%)	25(50%)	
	1	10(20%)	20(40%)	0.401
	2	5(10%)	5(10%)	
Day 15	0	45(90%)	31(62%)	
	1	0(0%)	14(28%)	0.615
	2	5(10%)	5(10%)	
At 1 month	0	45(90%)	45(90%)	0.432
At 1 month	1	5(10%)	5(10%)	0.432

Comparison of group 1 and group 2 on treatment for tearing on day 1, day 7, day 15 and at 1 month is not statistically significant.

**Table 4:** Comparison of Group 1 and Group 2 with Hyperemia on day 1, day 7, day 15 and at 1 month on treatment with Bepotastine besilate 1.5% & Olopatadine Hcl 0.1% respectively.

Hyperemia				
Time	Grading	Group 1 (Bepotastine Besilate 1.5%)	Group 2 (Olopatadine HCl 0.1%)	P value
Day 1	1	25(50%)	25(50%)	
	2	20(40%)	20(40%)	0.112
	3	5(10%)	5(10%)	
Day 7	0	35(70%)	25(50%)	
	1	10(20%)	20(40%)	0.401
	2	5(10%)	5(10%)	
Day 15	0	45(90%)	31(62%)	
	1	0(0%)	14(28%)	0.615
	2	5(10%)	5(10%)	
At 1 month	0	45(90%)	45(90%)	0.432
	1	5(10%)	5(10%)	0.432

Comparison of group 1 and group 2 on treatment for Hyperemia on day 1, day 7, day 15 and at 1 month is not statistically significant.

**Table 5:** Comparison of Group 1 and Group 2 with Papillary hyperplasia on day 1, day 7, day 15 and at 1 month on treatment with Bepotastine besilate 1.5% & Olopatadine Hcl 0.1% respectively.

Papillary Hyperplasia				
Time	Grading	Group 1 (Bepotastine Besilate 1.5%)	Group 2 (Olopatadine HCl 0.1%)	P value
Day 1	0	25(50%)	25(50%)	
	2	20(40%)	20(40%)	0.112
-	3	5(10%)	5(10%)	
Day 7	0	25(50%)	25(50%)	
	1	20(40%)	20(40%)	0.112
	2	5(10%)	5(10%)	
Day 15	0	45(90%)	31(62%)	
	1	0(0%)	14(28%)	0.615
	2	5(10%)	5(10%)	1
At 1 month	0	45(90%)	45(90%)	0.432
At 1 month	1	5(10%)	5(10%)	

Comparison of group 1 and group 2 on treatment for papillary hyperplasia on day 1, day 7, day 15 and at 1 month is not statistically significant.

**Table 6:** Comparison of Group 1 and Group 2 with Horner Tanta Spots on day 1, day 7, day 15 and at 1 month on treatment with Bepotastine besilate 1.5% & Olopatadine Hcl 0.1% respectively.

Horner Tranta Spots				
Time	Grading	Group 1 (Bepotastine Besilate 1.5%)	Group 2 (Olopatadine HCl 0.1%)	P value
Day 1	0	45(90%)	45(90%)	0.432
	3	5(10%)	5(10%)	
D 5	0	45(90%)	45(90%)	0.432
Day 7	3	5(10%)	5(10%)	
Day 15	0	45(90%)	45(90%)	0.422
	3	5(10%)	5(10%)	0.432
At 1 month	0	45(90%)	45(90%)	0.432
	3	5(10%)	5(10%)	0.432

Comparison of group 1 and group 2 on treatment for Horner tranta spots on day 1, day 7, day 15 and at 1 month is not statistically significant.

# Discussion

Table 1 shows distribution of study population according to their age groups in which group 1 has 29(58%) patients in age group 1-10yrs and 21(42%) patients were in 11-20yrs age group. In Group 2 30(60%) of patients are in age group 1-10yrs and 20(40%) patients were in 11-20yrs age group. Similarly a study conducted by Deep U, Chander A *et al.* included 100 patients in their study in which they divided into two groups, group 1 with bepotastine besilate 1.5% treatment and group 2 with loteprednol etabonate 0.5% treatment of which age distribution of study population in group 1 was 30(60%) patients belongs to age group 5-10yrs and 20(40%) belongs to age group 11-15yrs whereas in

group 2 29(58%) belongs to age group 5-10yrs and 21(42%) belongs to age group 11-15yrs  $^{[20]}$ . Malahat AR, Kodudula S, Gali VL  $^{[21]}$  done a study which included 50 patients for their study of which 36(72%) belongs to age group 5-10yrs and 14(28%) belong to age group 11-15yrs which is similar to another study done by Sruthi V, Reddy RN  $\it et al$  involved 50 patients in the study of which 36(72%) belongs to age group 5-10yrs and 14(28%) belong to age group 11-15yrs respectively  $^{[22]}$ .

Gender distribution in both groups was similar in this study as shown in figure 1 & 2. Boys are 30(60%) and Girls are 20(40%) in both groups respectively. Deep U, Chander A *et al.* [20] had included 100 patients in their study in which they

divided into two groups, group 1 with bepotastine besilate 1.5% treatment and group 2 with loteprednol etabonate 0.5% treatment in which Males are 31(62%) and females are 19(38%) in group 1 and males are 30(60%) and females are 20(40%) in group 2 which is similar to this study  $^{[20]}$ . Malahat AR, Kodudula S, Gali VL $^{21}$  done a study in which they included 50 patients for their study of which 39(78%) are males and 11(22%) were females which was same as Sruthi V, Reddy RN  $et\ al.$  which involved 50 patients in the study of which 39(78%) are males and 11(22%) were females respectively  $^{[22]}$ 

Table 2 showing comparison of VKC patients of Group 1 and Group 2 with Itching on day 1, day 7, day 15 and at 1 month on treatment with Bepotastine besilate 1.5% & Olopatadine Hcl 0.1% respectively shows that on day 1 25(50%) in grade 1 itching, 20(40%) in grade 2 itching and 5(10%) in grade 3 itching in group 1 and similarly 25(50%) in grade 1 itching, 20(40%) in grade 2 itching and 5(10%) in grade 3 itching in group 2 also which is not statistically significant(p=0.112). On Day 7 both groups show similar results on treatment with 25(50%) in no itching, 20(40%) in grade 1 itching and 5(10%) in grade 2 itching which is also not statistically significant (p=0.112). On day 15, both groups show similar results on treatment with 45(90%) shows no itching and 5(10%) shows grade 2 itching which is statistically insignificant(0.432). On treatment for 1 month both groups show similar results with 45(90%) has relieved from itching and 5(10%) were having grade 1 itching after 1 month treatment which is statistically insignificant (0.432). Both drugs acted similarly on onset and had same efficacy on treatment for Itching. Deep U, Chander A et al. conducted a study in which group 1 with bepotastine besilate 1.5% treatment on day 1 showed 26(52%) with grade 1 itching, 20(40%) with grade 2 itching and 4(8%) with grade 3 itching whereas in group 2 on day 1 showed 28(56%) with grade 1 itching and 22(44%) with grade 2 itching which is statistically insignificant. On day 7 6(12%) had no itching, 32(64%) grade 1 itching and 12(24%) grade 2 itching in group 1 and in group 2 12(24%) are with no itching, 35(70%) in grade 1 itching and 3(6%) in grade 2 itching which is statistically significant. On day 15 in group 1 22(44%) had no itching, 20(40%) had grade 1 itching and 8(16%) had grade 2 itching where as in group 2 33(66%) had no itching and 17(34%) had grade 1 itching which is statistically highly significant. loteprednol etabonate 0.5% is superior than bepotastine besilate 1.5% in relieving itching [20]. Malahat AR, Kodudula S, Gali VL [21] done a study in which they included 50 patients in which they gave the responders for each follow up visit. Out of 25 patients in group A (Olopatadine Hcl 0.1%) 16% with no itching on 1st follow up, 28% with no itching on 2nd follow up and 48% with no complaints of itching on treatment during 3<sup>rd</sup> follow up where as in group B(bepotastine besilate 1.5%) 8% with no itching on 1st follow up, 40% with no itching on 2nd follow up and 48% with no complaints on treatment during 3<sup>rd</sup> follow up visit <sup>[21]</sup>.

Table 3 showing comparison of VKC patients of Group 1 and Group 2 with tearing on day 1, day 7, day 15 and at 1 month on treatment with Bepotastine besilate 1.5% & Olopatadine Hcl 0.1% respectively depicts on day 1 25(50%) has grade 1 tearing, 20(40%) has grade 2 tearing and 5(10%) has grade 3 tearing in group 1 and in group 2 shows similar results on day 1 with 25(50%) has grade 1 tearing, 20(40%) has grade 2 tearing and 5(10%) has grade

3 tearing which is statistically insignificant(0.112). On day 7 35(70%) had no tearing, 10(20%) had grade 1 tearing and 5(10%) had grade 2 tearing in group 1 whereas in group 2 25(50%) had no tearing, 20(40%) had grade 1 tearing and 5(10%) had grade 2 tearing but it is statistically insignificant (0.401). During day 15 follow up visit in group 1, 45(90%) not having tearing and 5(10%) had grade 2 tearing whereas in group 2 31(64%) had no tearing, 14(28%) had grade 1 tearing, 5(10%) had grade 2 tearing which is statistically insignificant (0.615). At 1 month follow up visit 45(90%) had no tearing, 5(10%) had grade 1 tearing in group 1 whereas in group 2 also same results are seen but statistically insignificant (0.432). Hence Bepotastine besilate 1.5% had early in onset of action and had good efficacy in reducing tears when compared to Olopatadine Hcl 0.1% treated patients. Similarly a study conducted by Malahat AR, Kodudula S, Gali VL [21] included 50 patients in which they gave the responders(grade 0/no symptoms or signs) for each follow up visit. In their study tearing had been relieved in 16%, 20% and 76% in first follow up, 2<sup>nd</sup> follow up and 3<sup>rd</sup> follow up respectively in group A(olopatadine) whereas in group B(bepotastine) tearing had been relieved in 24%, 56% and 88% in first follow up, 2<sup>nd</sup> follow up and 3<sup>rd</sup> follow up respectively which shows significant results in second follow up visit which is not consistent with this study [21]. Craig F McCabe, Shannon E McCabe conducted a study which showed that 56.7% of patients chose Bepotastine besilate and 43.3% (13/30) chose Olopatadine as the preferred agent for tearing relief. Their analysis is consistent with Malahat AR et al. study but not with this study [19]. Table 4 showing the comparison of VKC patients of Group 1 and Group 2 with Hyperemia on day 1, day 7, day 15 and at 1 month on treatment with Bepotastine besilate 1.5% & Olopatadine Hcl 0.1% respectively depicts on day 1, 25(50%) having grade 1 hyperemia, 20(40%) has grade 2 hyperemia and 5(10%) has grade 3 hyperemia in group 1 whereas in group 2, 25(50%) having grade 1 hyperemia, 20(40%) has grade 2 hyperemia and 5(10%) has grade 3 hyperemia which is statistically insignificant(0.112). Day 7 in group 1, 35(70%) had no hyperemia, 10(20%) has grade 1 hyperemia and 5(10%) has grade 2 hyperemia whereas in group 2 25(50%) has no hyperemia, 20(40%) grade 1 hyperemia and 5(10%) grade 12 hyperemia which is statistically insignificant(0.401). Day 15 in group 1, 45(90%) has no hyperemia noted, 5(10%) had grade 2 hyperemia whereas in group 2 31(64%) had no hyperemia, 14(28%) has grade 1 hyperemia and 5(10%0 has grade 2 hyperemia which is statistically insignificant (0.615). After 1 month, in group 1 45(90%) has no hyperemia and 5(10%) had grade 1 hyperemia and group 2 also same result is seen with 45(90%0) has no hyperemia and 5(10%) has hyperemia which is statistically insignificant (0.432). Hence Bepotastine besilate 1.5% is quick in onset of action but by end of one month of treatment both drugs are equally efficacious. Similarly a study conducted by Malahat AR, Kodudula S, Gali VL included 50 patients in which they gave the responders(grade 0/no symptoms or signs) for each follow up visit. In their study 8%, 36% and 100% responded to treatment well in group A(olopatadine) on 1st, 2nd and 3rd follow up visit respectively whereas in group B(bepotastine) 28%, 76% and 100% responded to treatment on 1st, 2nd and

3<sup>rd</sup> follow up visit respectively which is inconsistent with

this study [21].

Table 5 showing the comparison of VKC patients of Group 1 and Group 2 with papillary hyperplasia on day 1, day 7, day 15 and at 1 month on treatment with Bepotastine besilate 1.5% & Olopatadine Hcl 0.1% respectively depicts on day 1 in group 1, 25(50%) had no papillary hyperplasia, 20(40%) had grade 2 papillary hyperplasia and 5(10%) had grade 3 papillary hyperplasia whereas in group 2 is same as group 1 with 25(50%) had no papillary hyperplasia, 20(40%) had grade 2 papillary hyperplasia and 5(10%) had grade 3 papillary hyperplasia which is statistically insignificant(0.112). Day 7 in group 1, 25(50%) had no papillary hyperplasia, 20(40%) had grade 1 papillary hyperplasia and 5(10%) had grade 2 papillary hyperplasia whereas in group 2 25(50%) had no papillary hyperplasia, 20(40%) had grade 1 papillary hyperplasia and 5(10%) which is statistically insignificant (0.112). Day 15 in group 1, shows 45(90%) with no papillary hyperplasia and 5(10%) grade 2 papillary hyperplasia whereas in group 2, 31(64%) has no papillary hyperplasia, 14(28%) has grade 1 hyperplasia and 5(10%) has papillary hyperplasia which is statistically insignificant (0.615). After 1 month of treatment in group 1 45(90%) had no papillary hyperplasia and 5(10%) had grade 1 hyperplasia whereas in group 2 45(90%) had no papillary hyperplasia and 5(10%) had grade 1 hyperplasia which is statistically insignificant (0.432). Hence Bepotastine besilate 1.5% has similar action like Olopatadine Hcl 0.1% in treating papillary hyperplasia. Similarly a study conducted by Malahat AR, Kodudula S, Gali VL included 50 patients in which they gave the responders(grade 0/no symptoms or signs) for each follow up visit in which group A patients treated with olopatadine eye drops showed that 36%, 40% and 64% had relieved from papillary hypertrophy by 1st follow up visit, 2nd and 3rd visit respectively whereas group B patients treated with bepotastine eye drops showed that 28%, 44% and 52% had relieved from papillary hypertrophy by 1st follow up visit, 2<sup>nd</sup> and 3<sup>rd</sup> visit respectively which were inconsistent with this study [21].

Table 6 showing the comparison of VKC patients of Group 1 and Group 2 with Horner tranta spots on day 1, day 7, day 15 and at 1 month on treatment with Bepotastine besilate 1.5% & Olopatadine Hcl 0.1% respectively depicts that in group 1 45(90%) has no horner tranta spots and 5(10%) had grade 3 horner tranta spots on day 1 follow up visit whereas in group 2, 45(90%) has no horner tranta spots and 5(10%) had grade 3 horner tranta spots which is statistically insignificant(0.432).On day 7 in group 1 45(90%) has no horner tranta spots and 5(10%) had grade 3 horner tranta spots whereas in group 2, 45(90%) has no horner tranta spots and 5(10%) had grade 3 horner tranta spots which is statistically insignificant(0.432). on day 15 in group 1, 45(90%) has no horner tranta spots and 5(10%) had grade 3 horner tranta spots whereas in group 2, 45(90%) has no horner tranta spots and 5(10%) had grade 3 horner tranta spots which is statistically insignificant(0.432). after 1 month of treatment in group 1, 45(90%) has no horner tranta spots and 5(10%) had grade 3 horner tranta spots whereas in group 2, 45(90%) has no horner tranta spots and 5(10%) had grade 3 horner tranta spots which is also statistically insignificant(0.432). Hence Bepotastine besilate 1.5% & Olopatadine Hcl 0.1% drugs both are ineffective in treatment of horner tranta spots.

No adverse effects were observed in both the groups A and B treated with Bepotastine besilate and Olopatadine respectively.

#### Conclusion

- Best method to prevent the disease is avoidance of allergen.
- Bepotastine besilate 1.5% & Olopatadine Hcl 0.1% had similar onset and equally efficacious in relieving Itching and papillary hyperplasia in VKC patients.
- Bepotastine besilate 1.5% was quick in onset and more efficacious than Olopatadine Hcl 0.1% in relieving tearing and hyperemia in VKC patients.
- Bepotastine besilate 1.5% & Olopatadine Hcl 0.1% had no efficacy in relieving Horner tranta spots
- No adverse effects were observed in both the groups A and B treated with Bepotastine besilate 1.5% and Olopatadine Hcl 0.1% respectively.
- As ours was a time bound study, sample size was restricted to 100 only and we could not study on larger population.

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