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Efficacy Of Haritaki And Shunthi Churna Bidalak In Vernal Keratoconjunctivitis

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Abstract
Vernal Keratoconjunctivitis (VKC) is a chronic, recurrent inflammatory disorder of the conjunctiva, primarily affecting children and young adults, characterized by severe ocular itching, redness, and photophobia. Conventional treatments, including corticosteroids and antihistamines, often have limitations due to side effects and recurrence. Ayurvedic formulations such as Haritaki and Shunthi Churna have demonstrated anti-inflammatory and immunomodulatory properties. This study aimed to evaluate the efficacy and safety of Haritaki and Shunthi Churna applied as Bidalak in managing symptoms of VKC. According to Ayurvedic principles, the spring season is when Kapha prakopa (Kapha vitiation) occurs, which is indicated by the name of the ailment, spring catarrh. The Kapha dominant stage of life is childhood, and the disease's clinical signs resemble those of Kaphaja Abhishyanda. Kaphaja Abhishyanda and VKC share a striking clinical similarity. Thus, there is an increasing need to understand the disease in view of Ayurveda and to establish the management through Ayurvedic system of medicine.
Keywords*: Ayurveda, Shalakya, Haritaki, Shunthi, Churna, Bidalak, Vernal Keratoconjunctivitis*

INTRODUCTION

Vernal Keratoconjunctivitis (VKC) is a chronic, seasonally recurring allergic eye disease predominantly affecting children and young adults in warm climates. It is characterized by intense itching, photophobia, foreign body sensation, and mucous discharge, which can severely impact quality of life. The pathophysiology of VKC involves a complex interplay of immunological mechanisms leading to conjunctival inflammation.

Current therapeutic approaches include antihistamines, mast cell stabilizers, and corticosteroids. However, long-term use of corticosteroids is associated with significant side effects such as increased intraocular pressure and cataract formation, necessitating alternative treatments with better safety profiles.

Ayurveda, the traditional Indian system of medicine, offers various herbal formulations with proven anti-inflammatory and immunomodulatory effects. Haritaki (Terminalia chebula) and Shunthi (Zingiber officinale) are two such herbs commonly used for their therapeutic properties in ocular conditions. This study investigates the clinical efficacy and safety of a combined herbal preparation of Haritaki and Shunthi Churna applied as Bidalak (ocular application) in patients with VKC.

AIMS AND OBJECTIVES

To evaluate the efficacy of *Haritaki* and *Shunthi Churna Bidalak* in the management of Vernal Keratoconjunctivitis.

MATERIALS AND METHODS

Type Of Study: Randomized Controlled Clinical Trial.

Materials:

Drug: Trial Group: *Haritaki* And *Shunthi Churna Bidalak*
Control Group: Olopatidine Eye Drop (0.1%)

METHTODOLOGY –

Patients: The grouping of patients was done as follows:

1. The study includes 56 patients.
2. They were divided into two groups of 28 patients in each group.

3. A separate case paper designed for evaluation of included patients.

- **Inclusion Criteria:**
- Patients suffering from Vernal Kerato Conjunctivitis.
- Age:12 to 20 years
- Gender : Both male and female
- **Exclusion Criteria:**
- Existing ocular surface pathology.
- One eyed patients.
- Post-operative patients.

Drug

Trial Group: Haritaki and Shunthi Churna Bidalak

Haritaki and *Shunthi churna* were prepared by standard method as mentioned below:

1. Required ingredients were collected from a proper *Ayurvedic* drug store.
2. Identification & Authentication of the raw drug was done at Sheetal Analytical Laboratory.
3. Standardization of raw drugs was done at Sheetal Analytical Laboratory.
4. SOP (Standard Operating procedure) for manufacturing were followed and then it was prepared as follows:

- Equal quantity of *Haritaki* and *Shunthi churna* was taken and were sieved from 60 no. sieve to make it into 60 mesh powder
- This powder was mixed, and stored in air tight container.
- Then powder was packed and stored in 6gm sealed plastic pouches each.

Dose and Time of Application

- **Trial Group (A)**: *Haritaki* and *Shunthi Churna Bidalak*
- Study Participants: - 28.
- These patients will be given *Haritaki* and *Shunthi Churna Bidalak* once daily for 7 days in morning.
- **Control Group (B):** Olopatidine eye drop (0.1%)
- Study Participants: - 28.
- These patients will be given olopatidine eye drops.
- Drug dose – 1 drop 3 times a day for 7 days.

Follow up-

- The study will be conducted for 28 days for both trial and control group.
- Haritaki and Shunthi churna Bidalak will be done once daily and Olopatidine eye drop (0.1%) TID will be administered for a period of 7 days regularly
- And a follow up will be taken on 15th day and 28th day.

Observations-

Gradation of symptoms:
0 - Normal

Sr.No.	**Signs and Symptoms**	0th day	7th day	14th day	28th day
1.	Itching				
2.	Burning sensation				
3.	Redness				
4.	Photophobia				
5.	Lacrimation				

+ - Mild
++ - Moderate
+++ - Severe

Gradation for Itching:
Gradation for Burning sensation:

INTENSITY		CRITERIA OF GRADATION
Normal	0	No Burning
Mild	+	Present, but not continuously disturbing
Moderate	++	Slightly present but continuously disturbing
Severe	+++	Distressing &interfering with daily life

Gradation for Redness:

INTENSITY		CRITERIA OF GRADATION
Normal	0	No itching
Mild	+	Occasional itching
Moderate	++	Frequent itching disturbing routine activity
Severe	+++	Constant itching disturbing sleep

INTENSITY		CRITERIA OF GRADATION
Normal	0	White bulbar conjunctiva.
Mild	+	Small increase in conjunctival redness. Major vessel more engorged.
Moderate	++	Conjunctiva very red. Increased limbal redness. Cillary flush.
Severe	+++	Conjunctiva extremely red. Limbus very red. Intense cillary flush. Reflex on major vessel.

Gradation for Photophobia:

INTENSITY		CRITERIA OF GRADATION
Normal	0	No Photophobia.
Mild	+	Mild reflex to torch light.
Moderate	++	Need of dark goggles.
Severe	+++	Extreme photophobia even after wearng dark goggles.

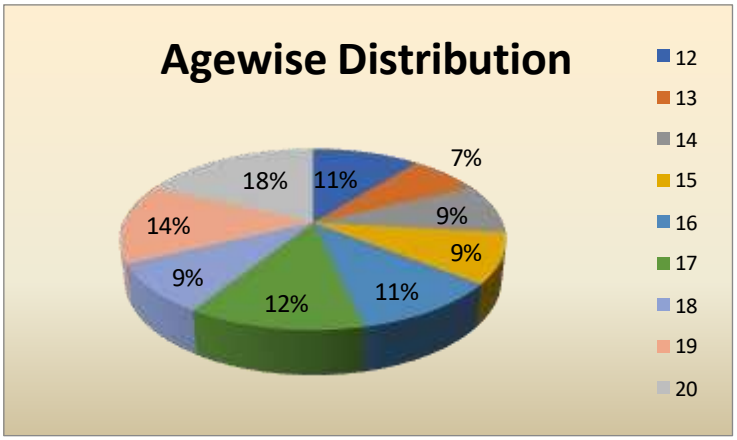
Gradation for Lacrimation:
Gradation for Conjunctival Hyperemia:
Gradation for Papillae:

INTENSITY		CRITERIA OF GRADATION
Normal	0	No Lacrimation.
Mild	+	Occasional lacrimation.
Moderate	++	Lacrimation but not hampering day to day life.
Severe	+++	Very uncomfortable need to wipe of continuously.

OBSERVATION AND RESULTS
Age wise Distribution

Age	Group A	Group B	Total
12	4	2	6
13	2	2	4
14	2	3	5
15	2	3	5
16	3	3	6
17	3	4	7
18	2	3	5
19	3	5	8
20	7	3	10
Total	**28**	**28**	**56**

Showing Incidence of Age



From above table we found that maximum numbers of patient's age was 20 years.

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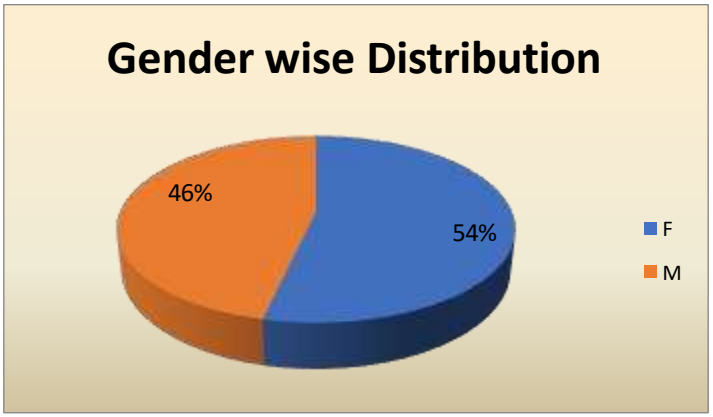
Gender Wise Distribution

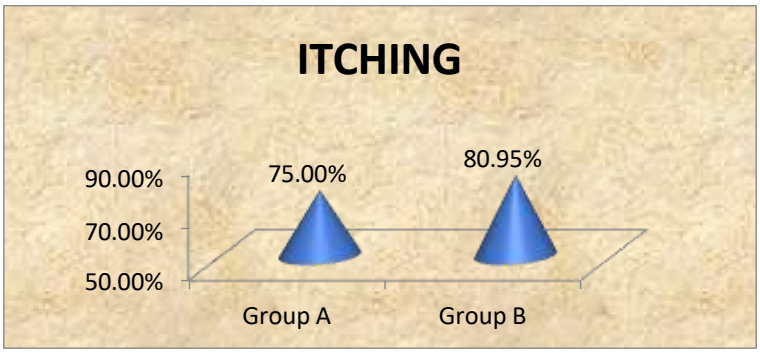
Gender	Group A	Group B	Total
F	13	17	30
M	15	11	26
Total	**28**	**28**	**56**

Showing Incidence of Gender



From above table we found that in this study maximum no of patients were Females.

COMPARISON OF GROUP A AND GROUP B ON ITCHING IN THE MANAGEMENT OF VERNAL KERATO CONJUNCTIVITIS



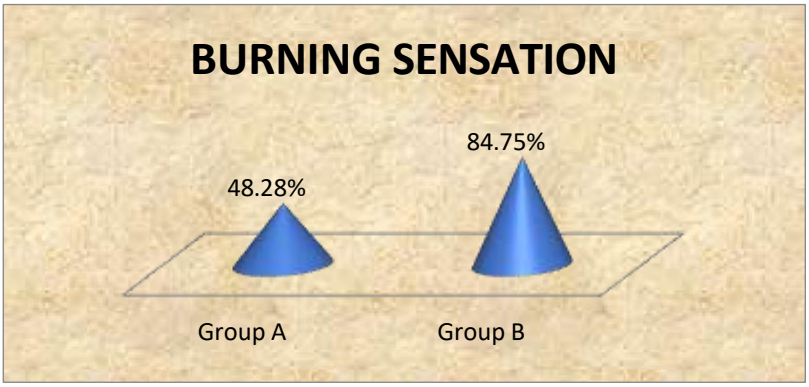
Comparison of trial and control group on itching in the management of vkc

Parameter	Group	% of improvement	Mann Whitney u	z	P VALUE
ITCHING	Group A	75.00%	322.00	-1.325	0.185
	Group B	80.95%			

Comparison of trial and control group on itching in the management of vkc

As p value>0.05 we found that there was no statistical significant difference between Group A and Group B on ITCHING in the management of Vernal Kerato Conjunctivitis.i.e Effect of Group A was same as Group B on ITCHING in the management of Vernal Kerato Conjunctivitis But as percentage of improvement seen from above table we get percentage of improvement in Group B was more than Group A hence we can say that **Group B is more effective as compared to Group A on ITCHING in the management of Vernal Kerato Conjunctivitis.**

COMPARISON OF GROUP A AND GROUP B ON BURNING SENSATION IN THE MANAGEMENT OF VERNAL KERATO CONJUNCTIVITIS



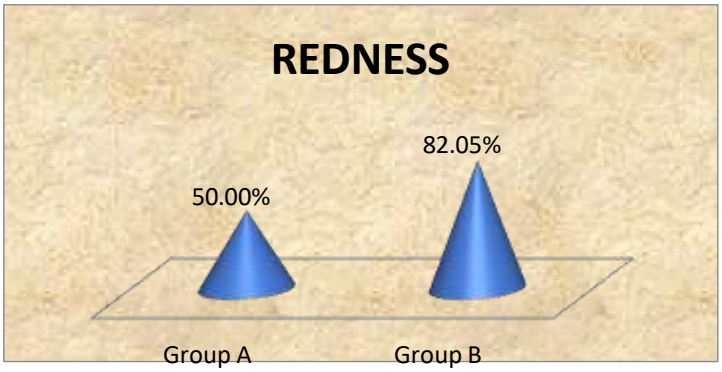
Comparison of trial and control group on burning sensation in the management of vkc

Parameter	Group	% of improvement	Mann whitney u	z	P VALUE
BURNING SENSATION	Group A	48.28%	183.50	-3.721	0.000
	Group B	84.75%			

Comparison of trial and control group on burning sensation in the management of vkc

As p value<0.05 we found that there was statistically significant difference between Group A and Group B on BURNING SENSATION in the management of Vernal Kerato Conjunctivitis Also as percentage of improvement seen from above table we get percentage of improvement in Group B was more than Group A hence we can say that **Group B is more effective as compared to Group A on BURNING SENSATION in the management of Vernal Kerato Conjunctivitis**

COMPARISON OF GROUP A AND GROUP B ON REDNESS IN THE MANAGEMENT OF VERNAL KERATO CONJUNCTIVITIS



Comparison of trial and control group on redness in the management of vkc

Parameter	Group	% of improvement	Mann whitney u	z	P VALUE
REDNESS	Group A	50.00%	154.00	-4.224	0.000
	Group B	82.05%			

Comparison of trial and control group on redness in the management of vkc

As p value<0.05 we found that there was statistical significant difference between Group A and Group B on REDNESS in the management of Vernal Kerato Conjunctivitis**.** Also as percentage of improvement seen from above table we get percentage of improvement in Group B was more than Group A hence we can say that **Group B is more effective as compared to Group A on REDNESS in the management of Vernal Kerato Conjunctivitis.**

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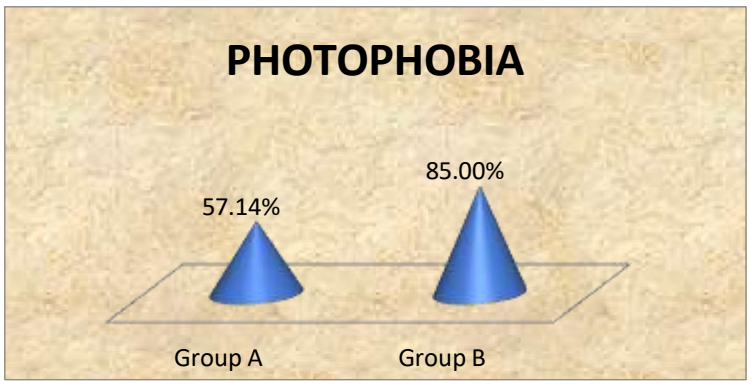
COMPARISON OF GROUP A AND GROUP B ON PHOTOPHOBIA IN THE MANAGEMENT OF VERNAL KERATO CONJUNCTIVITIS



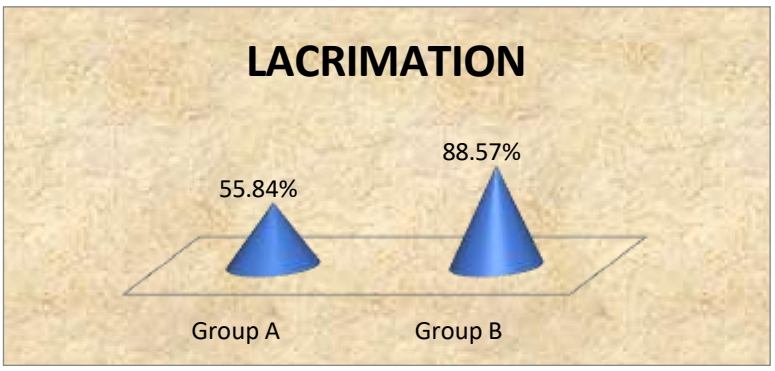
Comparison of trial and control group on photophobia in the management of vkc

Parameter	Group	% of improvement	Mann whitney u	z	P VALUE
PHOTOPHOBIA	Group A	57.14%	321.00	-1.469	0.142
	Group B	85.00%			

Comparison of trial and control group on photophobia in the management of vkc

As p value<0.05 we found that there was statistical significant difference between Group A and Group B on PHOTOPHOBIA in the management of Vernal Kerato Conjunctivitis. Also as percentage of improvement seen from above table we get percentage of improvement in Group B was more than Group A hence we can say that **Group B is more effective as compared to Group A on PHOTOPHOBIA in the management of Vernal Kerato Conjunctivitis.**

COMPARISON OF GROUP A AND GROUP B ON LACRIMATION IN THE MANAGEMENT OF VERNAL KERATO CONJUNCTIVITIS



Comparison of trial and control group on lacrimation in the management of vkc

Parameter	**Group**	**% of improvement**	**Mann whitney u**	**z**	**P VALUE**
LACRIMATION	Group A	55.84%	166.00	-4.015	0
	Group B	88.57%			

Comparison of trial and control group on lacrimation in the management of vkc

As p value<0.05 we found that there was statistical significant difference between Group A and Group B on LACRIMATION in the management of Vernal Kerato Conjunctivitis. Also as percentage of improvement seen from above table we get percentage of improvement in Group B was more than Group A hence we can say that **Group B is more effective as compared to Group A on LACRIMATION in the management of Vernal Kerato Conjunctivitis.**

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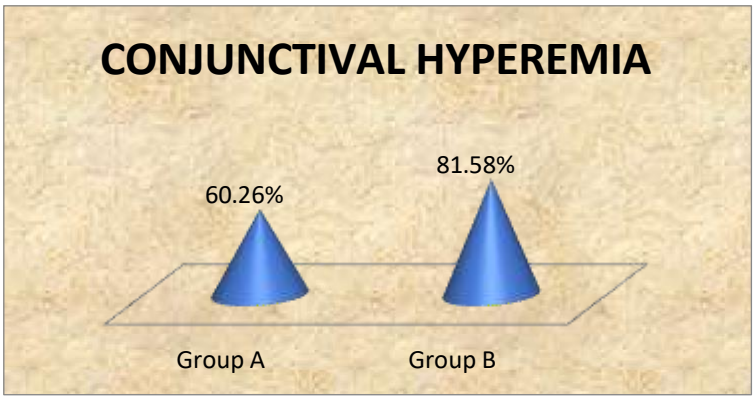
COMPARISON OF GROUP A AND GROUP B ON CONJUNCTIVAL HYPEREMIA IN THE MANAGEMENT OF VERNAL KERATO CONJUNCTIVITIS



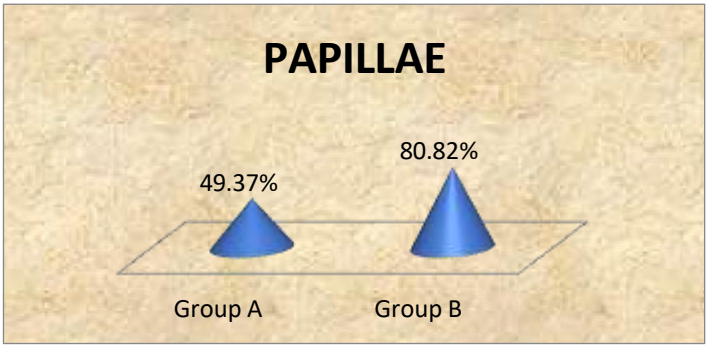
Comparison of trial and control group on conjunctival hyperemia in the management of vkc

PARAMETER	Group	% of improvement	Mann whitney u	Z	P VALUE
CONJUNCTIVAL HYPEREMIA	Group A	60.26%	239.50	-2.68	0.01
	Group B	81.58%			

Comparison of trial and control group on conjunctival hyperemia in the management of vkc
Mann-Whitney U test revealed a statistically significant difference (p=0.01) between the two groups. The **percentage improvement was higher in Group B (81.58%) compared to Group A (60.26%)**.

Hence, **Group B was more effective than Group A in reducing Conjunctival Hyperemia**.

COMPARISON OF GROUP A AND GROUP B ON PAPILLAE IN THE MANAGEMENT OF VERNAL KERATO CONJUNCTIVITIS



Comparison of trial and control group on papillae in the management of vkc

PARAMETER	**Group**	**% of improvement**	**Mann whitney u**	**z**	**P VALUE**
PAPILLAE	Group A	49.37%	168.00	-3.90	0.00
	Group B	80.82%			

Comparison of trial and control group on papillae in the management of vkc
Mann-Whitney U test revealed a significant difference (p=0.00) between the groups. The **percentage improvement in Group B (80.82%) was much higher compared to Group A (49.37%)**. Hence, **Group B was more effective than Group A in reducing Papillae in vernal kerato conjunctivitis.**

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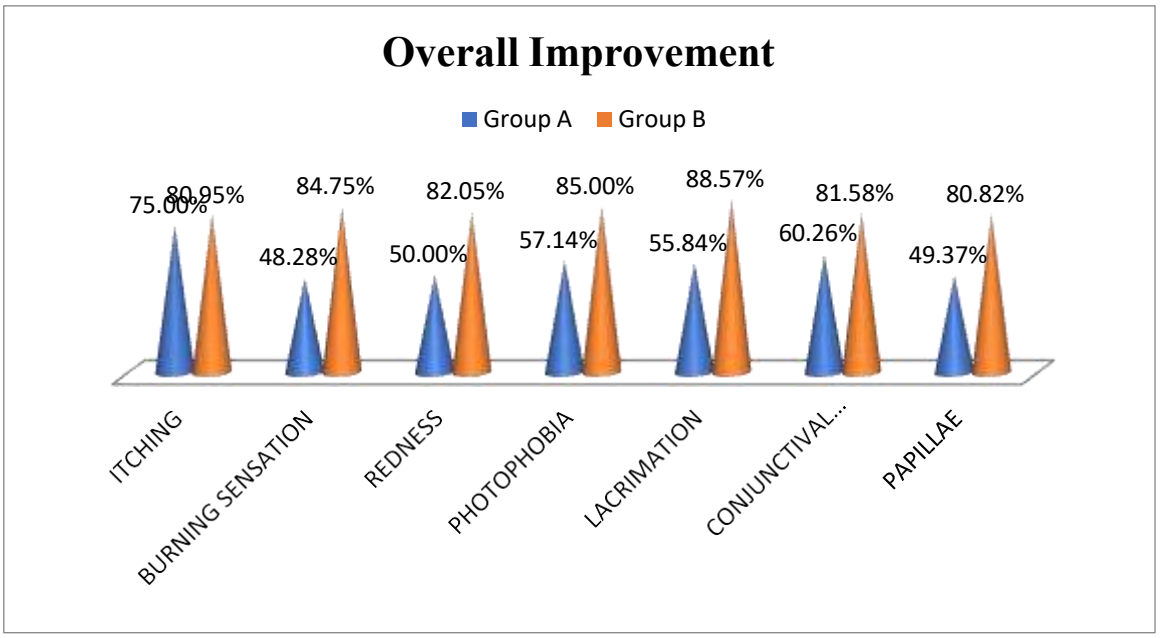
OVERALL IMPROVEMENT



Showing overall improvement of trial and control group in the management of VKC

Both **Group A (*Haritaki* and *shunthi churna bidalak*)** and **Group B (Olopatidine eye drop)** treatments were effective in the management of **Vernal Kerato Conjunctivitis**, showing statistically significant improvement in all major signs and symptoms such as **Itching, Burning Sensation, Redness, Photophobia, Lacrimation, Conjunctival Hyperemia, and Papillae**.

- **Group A** showed gradual but consistent improvement across all parameters, with percentage improvements ranging between **36–75%** at 28 days.
- **Group B** demonstrated comparatively faster and higher improvement, with percentage improvements ranging between **60–88%** at 28 days.
- On direct statistical comparison, **Group B showed significantly better results** than Group A in **Burning Sensation, Redness, Lacrimation, Conjunctival Hyperemia, and Papillae** ($p<0.05$).
- For **Itching and Photophobia**, both groups were effective, and the difference was not statistically significant, although Group B still showed higher percentage improvement.

Thus, it can be concluded that **both regimens are effective**, but **Group B (Olopatidine eye drop)** is **more effective than Group A (*Haritaki* and *shunthi churna bidalak*)** in the overall management of **Vernal Kerato Conjunctivitis**.

DISCUSSION

- The present randomized controlled clinical trial was conducted to evaluate the therapeutic and clinical efficacy of *Haritaki* and *Shunthi Churna Bidalak* and Olopatadine (0.1%) eye drop in the management of Vernal Kerato conjunctivitis.
- VKC is a recurrent, allergic, and predominantly Kaphaja eye disorder as per *Ayurvedic* understanding. In *Ayurvedic* texts, VKC closely resembles *Kaphaja Abhishyanda*, characterized by symptoms such as itching, burning sensation, redness, photophobia, and lacrimation.
- The trial group, treated with *Haritaki* and *Shunthi Churna Bidalak*, showed some improvement in classical symptoms like *Kandu* (itching), *Daha* (burning sensation), and *Ashru Srava* (watering).
- The choice of drugs was based on their *Kapha-Pitta Shamak, Lekhana,* and *Shothahara* properties. *Haritaki* is renowned for its *Tridoshaghna* action and possesses *Rasayana* and anti-inflammatory effects. *Shunthi*, on the other hand, is known for its *Deepana, Pachana*, and *Vedanasthapaka* (analgesic) properties and helps in reducing local inflammation. No adverse reactions were noted, indicating the safety and local tolerability of the *Bidalak* therapy.
- The disease *Kaphaj Abhishyand* explained in various classics by our *Acharyas* so it cannot be attributed to one particular disease of modern science, certain *lakshanas* of *Kaphaj Abhishyand* appear to be similar to that of Vernal Kerato conjunctivitis and hence attempt was made to co-relate the *lakshanas* of *Kaphaj Abhishyand* to Vernal Kerato conjunctivitis.

In present study, 56 patients were selected and divided randomly into 2 groups of 28 patients in each.

Group-A (Trial group) –

Patients were advised for *Haritaki* and *Shunthi Churna Bidalak* for 7 days.

Group-B (Control group) –

Patients were advised for Olopatidine (0.1%) eye drop for 7 days.

The observation and results which was obtained out of 56 patients are discussed below.

Age -

The incidence of VKC was observed in the age group of 20 years. It is probably because of VKC seen in childrens.

Gender -

The incidence of VKC was observed higher in femals than males. It is probably because of maximum no. of patients were females in this study.

1. In Itching, Group A showed improvement with 75.00% while Group B showed improvement with 80.95%.
2. In Burning Sensation, Group A showed improvement with 48.28% while Group B showed improvement with 84.75%.
3. In Redness, Group A showed improvement with 50.00% while Group B showed improvement with 82.05%.
4. In Photophobia, Group A showed improvement with 57.14% while Group B showed improvement with 85.00%.
5. In Lacrimation, Group A showed improvement with 55.14% while Group B showed improvement with 88.57%.
6. In Conjunctival hyperemia, Group A showed improvement with 60.26% while Group B showed improvement with 81.58%.
7. In Papillae, Group A showed improvement with 49.37% while Group B showed improvement with 80.82%.

PROBABLE MODE OF ACTION:

The reduction in classical symptoms such as itching, lacrimation, redness is seen due to following probable mode of action of trial drug.

1. *Kapha Shamana*:

- *Haritaki*- Has *Kashaya* and *Ruksha* properties, which help in drying excessive *Kapha* secretions.
- *Shunthi*- Possesses *Katu* and *Ushna* properties, effective in breaking down *Kapha* and reducing *Srotorodha*.

2. *Lekhana* & *Shoshana*: Both drugs have *Lekhana* properties, which help in removing the sticky *Kapha* secretions from the ocular tissues.

3. Anti-inflammatory and Anti-allergic Activity (Modern Correlation):

- *Haritaki*- Contains chebulinic acid, gallic acid, and other tannins with anti-inflammatory and antioxidant properties, helping in reducing conjunctival swelling.
- *Shunthi*: Rich in gingerols and shogaols, which have proven anti-allergic, antihistaminic, and anti-inflammatory effects—especially useful in allergic conditions like VKC (vernal kerato conjunctivitis).

4. *Rasayana* and Immunomodulatory Effects:

- *Haritaki* acts as a *Rasayana*, enhancing local and systemic immunity, preventing recurrences.
- *Shunthi* boosts *Agni* and improves immunity, reducing *Ama*, which are often implicated in allergic manifestations.

5. The combined use of *Haritaki* and *Shunthi Churna* in *Kaphaj Abhishyand* helps by: Reducing *Kapha*-related secretions and inflammations of ocular surface. Providing antioxidant and anti-allergic effects. Preventing recurrence through *Rasayana* and immune-enhancing properties.

CONCLUSION

- Detail description about *Kaphaj Abhishyand* is found in *Brihatrayes*, as well as *Laghutrayees*.
- Etiological factors, symptoms and etiopathogenesis are almost similar in *Ayurveda* and Modern science.
- Group A showed nearly good response in *Kandu* (Itching) while showed some response in *Daha* (Burning sensation), *Ashrustrav* (Lacrimation), *Aaraktata* (Redness), and Photophobia. According to

statistical study, NULL HYPOTHESIS is accepted; therefore it can be concluded that the effect of Olopatidine (0.1%) eye drop is more effective than *Haritaki* and *Shunthi Churna Bidalak.*

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