ISSN: 2322 - 0902 (P)
ISSN: 2322 - 0910 (O)

International Journal of Ayurveda and Pharma Research

Research Article

A PILOT CLINICAL STUDY ON THE EFFICACY OF *BILVAMULADI KWATHA ASCHYOTANA* IN THE MANAGEMENT OF *KAPHAJ ABHISHYANDA* W.S.R.TO BACTERIAL CONJUNCTIVITIS

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Article info

Article History:
Received: 15-07-2023
Revised: 31-07-2023
Accepted: 26-08-2023

KEYWORDS:
Ashchyotana, Bacterial conjunctivitis*, Bilvamuladi Kwatha, Chakshushya, Kaphaja Abhishyanda*.

ABSTRACT

Bacterial conjunctivitis is one of the most common ocular diseases that occurs worldwide and affects every age group and social strata. The disease *Kaphaj Abhishyanda*, which is due to vitiation of *Kapha Pradhana Tridosha* is comparable with this condition. In the management of bacterial conjunctivitis as per modern ophthalmology antibiotic and antihistaminic eye drops are prescribed. Because of recurrent use of antibiotics, chances of antibiotic resistance are increasing. The present study was planned to evaluate the management of same disease with Ayurvedic formulation. Ayurveda can provide better alternative treatment in such manifestation. Ayurvedic formulation mentioned in *Ashtanga Sangraha* on *Kaphaj Abhishyanda* was selected and the *Bilwamuladi Kwatha* was prepared for *Aschyotana* as mode of administration. 3 patients diagnosed with *Kaphaj Abhishyanda* were selected and given *Bilwamuladi Kwatha Aschyotana* 1 drop twice a day for 7 days. The assessment of symptoms was done before, during the treatment and after treatment. The *Bilvamuladi Kwatha* has *Ushna Veerya* and *Kaphaghna* properties, which helps in treating vitiated *Kapha Dosha* as well as *Madhu* and *Shigru* are known to be *Chakshushya. Bilvamuladi Kwatha* was found effective with significantly reducing symptoms of *Kaphaj Abhishyanda* and shows marked difference in bacterial culture and sensitivity testing of conjunctival smear, which is studied as objective parameter.

INTRODUCTION

Abhishyanda is considered as the root cause of almost all the occular disorders and must be treated as early as possible, otherwise its complications will become severe and difficult to save the eyesight [1]. The word *Abhishyanda* is derived from *`Syanda'*, which means tremors (*Syandan-Kriya*) and *`Abhi'* meaning excessive. The *Syandan Kriya* results into *Kleda* formation in *Dosha-Dhatu-Malas* which further results into excessive pus-like secretions from eyes. These particular group of symptoms are categorized as *Netra-Abhishyanda.*

The symptoms of *Kaphaj Abhishyanda* like *Netra Shopha*, (oedema of eyes) *Guruta* (heaviness), *Kandu* (itching), *Pichchil Strav* (sticky discharge) [2] can be correlated with the symptoms of bacterial conjunctivitis which is characterized by conjunctival congestion due to dilation of vessels, resulting in hyperemia, chemosis i.e., oedema of conjunctiva and typically associated with mucoid or mucopurulent discharge. Viral conjunctivitis followed by bacterial conjunctivitis is most common cause of infectious conjunctivitis. Bacterial conjunctivitis is the second most common cause of infective conjunctivitis. The most common pathogen for bacterial conjunctivitis in adults is staphylococcal species. Mattering and adherence of the eyelids, cilia are usually matted together with crusts, itching and absence of family history of conjunctivitis are the strongest factors seen with cases of bacterial conjunctivitis[3].

According to modern medicinal science topical antibiotics are used to reduce severity and duration of the disease. Antibiotic can hasten the resolution of symptoms and microbial eradication, thus helps to reduce spread of a disease.

But besides all above conditions, all cases of acute conjunctivitis don't require antibiotic therapy. In

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Quick Response Code	
	https://doi.org/10.47070/ijapr.v11i8.2860

most uncomplicated cases, symptoms resolve in 1 to 2 weeks. And also high level of resistance was seen towards many antibiotics. Hence, there is scope to search for a better treatment from the rich heritage of Ayurveda where many ophthalmic preparations are described already.

Therefore to avoid this complications and to obtain a safe drug which is equally or more efficacious, which can be useful to treat bacterial conjunctivitis with Ayurvedic herbal medicines is the primary aim of this study trial. Hence to achieve this, controlled trial to evaluate the efficacy of *Bilvamuladi Kwatha* in the management of *Kaphaj Abhishyanda* is carried out.

Among various formulations prescribed for the treatment of *Kaphaja Abhishyanda* by different *Acharyas, Bilvamuladi Kwatha Aschyotana*, which is indicated in the treatment of *Kaphaja Abhishyanda* (bacterial conjunctivitis), had been selected in this study. This *BIlvamuladi Kwatha* is mentioned in 19th chapter of *Uttartantra* of *Ashtang Sangraha*[4]. It contains *Shigru* (*Moringa pterigosperma), Patala (Stereospermum suaveolence), Shunthi (Zingibare officinale) Bilva-Mula (Aegle marmelos)* have the *Kapha Shamaka* effect with *Madhu* (honey) as a *Prakshepa* having *Kaphaghna* and *Chakshushya* properties. Moreover all the ingredients are proven for their antibacterial and anti-inflammatory activities which help to relive the symptoms.

However, *Ashchyotana* is indicated in all ocular diseases as the foremost procedure[5]. The most common form of drug instillation in ophthalmic practice is eye drop, because of it maintains standard dose of drug and patients can conveniently carry it with them and instill it whenever required. Considering this, eye drop formulation of *Bilvamuladi Kwatha* has been chosen for *Aschyotana.*

Looking in to all these, a study is planned to evaluate the efficacy of *Bilvamuladi Kwatha Ashchyotana*.

AIMS AND OBJECTIVES

The present study has been undertaken with the following aim and objective:

To study the efficacy of *Bilvamuladi Kwatha Aschyotana* in the patients of *Kaphaj Abhishyanda.*

MATERIAL AND METHODS

Source of data: Patients with *Kaphaj Abhishyanda*, fulfilling the inclusion criteria attending the OPD of the *Shalakyatantra* Department of S.G.A.K. Hadapsar, Pune. A detailed research proforma was prepared as per the modern and Ayurvedic points. After taking ophthalmic and systemic history, a detailed conjunctival examination was carried out by torch, light and slit lamp, before and after the treatment.

Preparation of drug

Preparation of *Bilvamuladi Kwatha* is done in pharmacy at S.G.A.K. Hadapsar, Pune, in sterile conditions.

- The raw material required for the *Bilvamuladi Kwatha* preparation was taken from authentic source and standardization of all those contents was done.
- All the contents mentioned in the above table were taken in equal quantity.
- Authentication and standardization of raw drugs for *Bilvamuladi Kwatha* was done. Drugs include *Bharad* of *Shigru, Patala, Shunthi, Bilva-mula* and *Madhu.*

Table 1: Properties of Drug Used for Preparation of *Bilvamuladi Kwatha*.

Name of the drug	*Rasa*	*Vipaka*	*Veerya*	*Guna*	*Doshaghnata*	Parts being used
Shigru[6] *(Moringa oleifera)* Morngaceae	*Madhur, Tikta, Katu*	*Katu*	*Ushna*	*Chakshushya, Laghu, Ruksha, Tikshna*	*Vataghna Pittaghna*	*Beeja*
Patala[7] *(Stereospermum suaveolence)* Bignoniaceae	*Tikta, Kashaya*	*Katu*	*Anushna*	*Ruksha, Laghu*	*Kaphaghna Vataghna*	*Twaka*
Shunthi[8] *(Zingibare officiale)* Zinziberaceae	*Katu*	*Madhur*	*Ushna*	*Laghu, Snigdha, Pachak*	*Kaphaghna Vatahara*	*Kanda* (Rhizome)
Bilva[9] *(Aegle marmelos)* Rutaceae	*Katu, Tikta, Kashay*	*Katu*	*Ushna*	*Laghu, Snigdha, Tikshna*	*Kaphaghna Vataghna*	*Mula*
Madhu[10] (Honey)	*Katu*	*Madhur*	*Sheeta*	*Chakshushya, Laghu, Ruksha, Grahi, Lekhana*	*Kaphaghna*	*Madhu*

- *Kwatha* was prepared by preparation method mentioned by *Achyarya Sharangdhara* by taking Drug:water as 1:16. Boiled till the volume remains 1/8th of the volume[11].
- In this *Kwatha Madhu* was added in necessary quantity as mentioned by *Achyarya Sharangdhara* and was named as *Bilvamuadi Kwatha*[11].
- Prepared *Bilvamuladi Kwatha* was filtered through grade 1 qualitative filter paper which has pore size 11µm. [Figure 1].

Sterilization of Eye drop Containers and Dropper

Sterilization of plastic eye drop containers along with the dropper was done using Ethylene Oxide (Eto) sterilization process [Figure 2].

The trial drug, *Bilvamuladi Kwatha* was prepared in the Pharmacy, Sane Guruji Aarogya Kendra, Hadapsar, Pune. For the eye drop formulation, the filtration process was carried out in the pharmaceutical laboratory and packed in sterile containers by taking aseptic precautions [Figure 3].

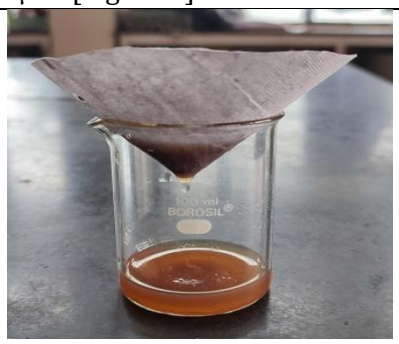

Figure1: Filtration of prepared *Bilvamuladi Kwatha*

Figure2: Eto-steralized bottle of Eye Drop

Figure3: Eye Drops with *Bilvamuladi Kwatha* filled in sterile condition

Inclusion Criteria

- Age in between 16 – 60 years
- Patients with signs and symptoms of *Kaphaja Abhishyanda* such as *Netra Guruta, Netra Kandu, Akshi Shopha, Picchil Strav* [2].

Exclusion Criteria

- Patients with *Vataja* and *Pittaj Abhishyanda*.
- Patients with any other ocular pathology like corneal ulceration, retinal disease.
- Patients having systemic illness like DM, HTN.
- Patients with immunosuppressive disorders like HIV.

Written and informed consent was taken from the patients.

Investigations

Culture and sensitivity test of conjunctival discharge.

Subjective Parameters

It was assessed by relief in the signs and symptoms of the *Kaphaja Abhishyanda* with scoring of 0 to 4 as follows.[12]

***Netra Guruta* (heaviness in eyes)**

0- No heaviness.
1- Heaviness is present and patient does not want regular movement of eyeball willingly.
2- Heaviness is present and patient does not want regular movement of eyeball unless it is necessary.
3- Heaviness is present but patient does not want regular movement of eyeball a little even if it is very necessary.

***Kandu* (Itching in eyes)**

0 - No incidence of itching
1- Occasional itching
2- Frequent itching
3- Continuous itching

***Picchil Strav* (Sticky discharge)**

0- No discharge
1- Small amount of mucoid discharge
2- Moderate amount of mucoid discharge
3- Eyelids tightly matted together on awaking

***Akshi Shopha* (oedema)**

0- No edema.
1- Edema present at 1/4th part of eye
2- Edema present at 1/2 part of eye
3- Edema present at 3/4th part of eye
4- Edema present in whole eye Observational table

Table 2 – Observation Table for Subjective Criteria for Each Patient

Lakshanas	**Day 0- Score**	**Day 3rd - Score**	**Day 7th – Score**
Netra Guruta (Heaviness in eyes)	0 – 3	0 - 3	0 – 3
Netra Kandu (Itching in eyes)	0 – 3	0 - 3	0 – 3
Pichchil Strav (Sticky discharge)	0 – 3	0 - 3	0 – 3
Akshi Shopha (Oedema)	0 – 4	0 - 4	0 – 4
Total Score	0 - 13	0 - 13	0 – 13

Observations were carried out before treatment, during the treatment i.e., during each follow up and after completion of treatment.

Objective Parameters

It was assessed by presence or absence of any bacteria in the conjunctival discharge smear examination pre and post treatment.

RESULTS AND DISCUSSION

Netra Abhishyanda is described as a contagious disease (*Aoupasargik Vyadhi*) by *Acharya Sushruta* because it can get transmitted through contact with the infected person in any and every possible way [13]. This explains the urgency to treat the disease to avoid further spread and complications. When *Kapha* gets aggravated and is localized inside the eyes it produces *Pichchil Strav* (mucoid discharge), *Upadeha* (stickiness over inner canthus), *Shopha* (mild oedema) known as *Kaphaj Abhishyanda.*

Observations

In the present study, observation was made by studying the clinical feature of 3 patients.

Table 3: Symptom wise Observational Scoring of Patients Before and After Study

Parameter's	Day 0	Day 3	Day 7
Patient 1			
1. *Netra Guruta*	02	01	00
2. *Netra Kandu*	03	01	01
3. *Pichchil Strav*	02	01	00
4. *Akshi Shopha*	02	00	00
5. Culture and Sensitivity test reports	Staphylococcus aureus (MSSA)	-	Coagulase Negative Staphylococcus (CONS)
Patient 2			
1. *Netra Guruta*	02	00	00
2. *Netra Kandu*	02	01	00
3. *Pichchil Strav*	01	01	00
4. *Akshi Shopha*	02	01	00
5. Culture and Sensitivity test reports	Staphylococcus aureus (MSSA)	-	No growth of any organism.
Patient 3			
1. *Netra Guruta*	01	01	00
2. *Netra Kandu*	01	01	00
3. *Pichchil Strav*	01	00	00
4. *Akshi Shopha*	01	00	00
5. Culture and Sensitivity test reports	Staphylococcus aureus (MSSA)	-	No growth of any organism

Results with Statistical Analysis

Acharya Vagbhata has explained in his context about effect of *Ushna Veerya* which acts as *Kaphaghna* due to its properties. *Ashtang Sangraha* states that contents of *Bilvamuladi Kwatha* acts with the similar properties as well as *Ruksha, Laghu Guna* of *Madhu* helps in treating the vitiated *Kapha Dhosha* as well as *Madhu* and *Shigru* are known to be *Chakshushya.*

Effect on *Netra Guruta*

Wilcoxon signed rank test:

Let,

M1: Symptoms before the treatment,

M2: Symptoms after the treatment

Null Hypothesis: There is no significant difference in symptoms before and after the treatment. M1=M2

Alternative Hypothesis: The symptoms after the treatment are significantly reduced than before the treatment. M2<M1

P value (after less than before)	0.0189
Estimated median difference (After-Before)	-2
95% confidence interval for difference	-2 to -2

P value (after less than before) <0.05

Decision: Reject the null hypothesis at 5% level of significance.

Conclusion: The symptoms after the treatment are significantly reduced than before the treatment.

Effect on *Netra Kandu*

Wilcoxon signed rank test:

Let, M1: Symptoms before the treatment,

M2: Symptoms after the treatment

Null Hypothesis: There is no significant difference in symptoms before and after the treatment. M1=M2

Alternative Hypothesis: The symptoms after the treatment are significantly reduced than before the treatment. M2<M1

P value (after less than before)	0.0189
Estimated median difference (After-Before)	-2
95% confidence interval for difference	-2 to -2

P value (after less than before) <0.05

Decision: Reject the null hypothesis at 5% level of significance.

Conclusion: The symptoms after the treatment are significantly reduced than before the treatment.

Effect on *Pichchil Strav*

Wilcoxon signed rank test:

Let, M1: Symptoms before the treatment

M2: Symptoms after the treatment

Null Hypothesis: There is no significant difference in symptoms before and after the treatment. M1=M2

Alternative Hypothesis: The symptoms after the treatment are significantly reduced than before the treatment.

M2<M1

P value (after less than before)	0.0286
Estimated median difference (After-Before)	-1
95% confidence interval for difference	-1 to -1

P value (after less than before) <0.05

Decision: Reject the null hypothesis at 5% level of significance.

Conclusion: The symptoms after the treatment are significantly reduced than before the treatment.

Effect on *Akshi shopha*

Wilcoxon signed rank test:

Let, M1: Symptoms before the treatment

M2: Symptoms after the treatment

Null Hypothesis: There is no significant difference in symptoms before and after the treatment. M1=M2

Alternative Hypothesis: The symptoms after the treatment are significantly reduced than before the treatment.

M2<M1

P value (after less than before)	0.0189
Estimated median difference (After-Before)	-2
95% confidence interval for difference	-2 to -2

P value (after less than before) < 0.05

Decision: Reject the null hypothesis at 5% level of significance.

Conclusion: The symptoms after the treatment are significantly reduced than before the treatment.

Probable Mode of Action

The contents of *Bilvamuladi Kwatha* are *Shigru, Patala, Shunthi, Bilva-mula* and *Madhu.* The *Shigru* has properties like *Ushna Veerya, Katu Vipaka,* and *Laghu Ruksha Tikshna Guna* which acts as *Kaphaghna*. Especially the *Beeja* of *Shigru* is known for its *Chakshushya* properties. Hence its acts by pacifying the *Kapha Dosha* as well as it will be beneficial to overall *Netra* with its *Chakshushya Guna.* Also *Patala, Shunthi* and *Bilva* have commonly *Laghu, Ruksha Guna* with all of them having *Kaphaghna* Properties which helps to decrease the *Netra Kandu* predominantly caused by aggravated *Kapha Dosha*. Additionally *Shunthi* having *Pachan Guna* and *Bilva* with *Tikshna Guna* helps to do *Shamana* as well as *Shodhana* of vitiated *Kapha. Madhu* was added in prepared *Kwatha* of above all contents according to *Sharangdhara Samhita* which states, in *Kaphaj Vyadhi, Madhu* should be added in 1/4th quantity of the total *Kwatha*[11]. *Madhu* is specially known for its *Kaphagna Guna* with its *Laghu, Ruksha* properties. The *Lekhan Guna* of *Madhu* additionally helps to reduce the *Picchil Strav* due to *Kapha.*

Acharya Vagbhata had mentioned 7 *Kriya-kalpa*. *Ashchyotana* is considered best from these 7 to treat ocular diseases, as it works on every structural abnormality of eye. The medicine instillation done in *Aschyotana* acts through the channeling of *Kosha, Sandhi, Sira, Shrungataka, Ghrana*, and *Strotasa*. Hence thereby it acts on vitiated *Doshas* present at *Netra.*

Hence *Bilvamuladi Kwatha Aschyotna* is selected for study to find effective treatment for *Kaphaj Abhishyanda.*

CONCLUSION

From this study it could be concluded that *Kaphaj Abhishyanda* is *Kapha* predominant type of *Netra Abhishyanda* which can be correlated with bacterial type of conjunctivitis with its signs and symptoms. According to modern medicinal science topical antibiotics are used to reduce severity and duration of the disease. Because of recurrent use of antibiotics, chances of antibiotic resistance are increasing. *Bilvamuladi Kwatha Aschyotana* shows satisfactory curative effects with reliving sign and symptoms. Also the bacterial study done on patients i.e., culture and sensitivity test in pre and post treatment shows significant results. No any adverse effect has been observed during the course of therapy.

Scope of Study

- Study can be done on large population as it has less to no adverse effects noted.
- *Kaphaj Abhishyanda* can be treated with other Ayurvedic formulations.

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Cite this article as:
Katwate Dipali Dipak, Kotangale Sumedha Yogesh. A Pilot Clinical Study on the Efficacy of Bilvamuladi Kwatha Aschyotana in the Management of Kaphaj Abhishyanda w.s.r. to Bacterial Conjunctivitis. International Journal of Ayurveda and Pharma Research. 2023;11(8):1-10.
https://doi.org/10.47070/ijapr.v11i8.2860
Source of support: Nil, Conflict of interest: None Declared

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