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CLINICAL TRIAL TO EVALUATE THE EFFICACY AND SAFETY OF *HARIDRADI ASHCYOTANA* (SRI LANKAN TRADITIONAL HERBAL EYE DROP) IN THE MANAGEMENT *ABHISHYANDA* W.S.R. BACTERIAL CONJUNCTIVITIS

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ABSTRACT: *Abhishyanda* is considered as a *Sankramika vyadhi* (contagious disease) with general features as *Netra srava* (lacrimation), *Samrambha* (swelling), *Raktata* (redness) and *Kandu* (itching). Bacterial conjunctivitis accounts for over 60% of all conjunctivitis cases with general features as redness, grittiness, burning and eye discharges. Present clinical study was conducted to evaluate the efficacy and safety of *Haridradi Ashcyotana* (HA): a Sri Lankan Traditional herbal eye drops in the management of *Abhishyanda* w.s.r. to Bacterial conjunctivitis. HA was prepared as per the standards mentioned in Ayurveda Pharmacopeia, Sri Lanka. Authentication and deposition of voucher samples of plant specimens were conducted while standardized HA for the safety and acceptability. Clinical trial was conducted after Institutional Ethics committee approval, in the *Shalakya* clinic, OPD of Ayurveda Teaching Hospital, Borella, Sri Lanka. Consecutive convenience sampling method was applied to register 20 patients of either gender, age between 10 – 70 years with clinical features of *Abhishyanda* w.s.r. to Bacterial conjunctivitis. Data analysis was done by SPSS 16.0. Enrolled patients were subjected to conjunctival smear swab culture which proved the antibacterial property of HA against *Staphylococcus aureus* and *Escherichia coli*. HA revealed highly significant 'p' values ($p < 0.001$) with 100% remission of all inflammatory features of the eye/s while total mean days for complete remission was 4.45. Drug related adverse effects were not observed and tolerability was good. Thus, can be concluded as *Haridradi Ashcyotana* is a safe, tolerable, quick action and effective herbal ophthalmic preparation for the management of *Abhishyanda* w.s.r. to Bacterial conjunctivitis.
Key-words: Antibacterial, conjunctival, smear, swab culture, lacrimation, remission

INTRODUCTION: *Abhishyanda* is a disease categorized under *Sarvagata Netra roga* in Ayurveda, altering the fluids of the eye with excessive discharges of the eye, swelling, redness, photophobia and the end feature can be suppuration in advance stage. *Abhishyanda* is four types categorized as *Vataja*, *Pittaja*, *Kaphaja* and *Raktaja* according to the specific *Dosha* predominance of the manifestation[1], hence the clinical entity possesses the similarity of conjunctivitis. The syndrome of acute 'red

eye' accounts for between 1% - 4% of consultations with primary care physicians, and results from one of several possible conditions viz. viral, bacterial and allergic conjunctivitis[2]. Bacterial conjunctivitis is a common presentation in general practice which affects both genders, all ages and races. Generally considered to be a self-limiting disorder, topical eye drops are nevertheless usually prescribed in the belief that they speed recovery, reduce the risk of developing sight-threatening complications and reduce the rate of re-infection[2]. Bacterial conjunctivitis may be caused by a wide range of organisms where most common bacterial pathogen of conjunctivitis in the environment is *Staphylococcus aureus*, being responsible for 74.9% of all cases [3]. In all eye diseases the first line of treatment is *Ashcyotana* (eye drops) which alleviates all inflammatory features with resolution of the disease[4]. In Sri Lankan Traditional Medicinal system conjunctivitis is termed as '*As ruja*' or '*Ase ratha*' which present with the common clinical features as lacrimation, redness, itching and photophobia[5,7]. Today most of the infective ocular pathologies are treated with modern topical preparations where prolong usage may lead to drug resistance. Though effective herbal preparations have been used for centuries in Traditional Medicinal systems, evidence based scientific approach lacks[6]. Further evidence shows that Ayurveda and Sri Lankan Traditional Medicinal system research on *Ashcyotana* (herbal eye drops) are mainly based on reviews, single case studies and reports and lacking of clinical studies. It is a timely necessity to address the gaps in the field of research pertaining to herbal ophthalmic preparations in Ayurveda and Sri Lankan Traditional Medicinal systems by undertaking scientific clinical research. Also, WHO promotes Traditional medicine in the countries to identify safe and effective herbal medicines for use in National health care systems[6]. The present study was designed to shed a scientific approach in validating and reestablishing the credibility of a herbal eye drop formulation used in Sri Lankan Traditional Ophthalmology in the management of *Abhishyanda* with special reference to Bacterial conjunctivitis.

METHODOLOGY

AIMS AND OBJECTIVES OF THE STUDY

General objective:

To evaluate the efficacy and safety of *Haridradi Ashcyotana* in the management of *Abhishyanda* w.s.r. to Bacterial conjunctivitis.

Specific objectives:

- To evaluate the quality control parameters of *Haridradi Ashcyotana*.
- To assess the anti-inflammatory effect of *Haridradi Ashcyotana*.
- To assess the anti-bacterial effect of *Haridradi Ashcyotana*.

Drug authentication and deposition of voucher samples

Establishment of correct Botanical identification of plant specimens, authentication and deposition of voucher samples were conducted at Bandaranaike Memorial Ayurveda Research Institute, *Maharagama*, Sri Lanka under following Accession numbers: 1569, 1570, 1571,1572,1573,1574.

Selection of the formula[7]

Pharmacognostically pure and authentic ingredients were used to prepare *Haridradi*

Ashcyotana (HA) as per standards mentioned in Ayurveda Pharmacopeia – Sri Lanka[7] at Faculty of Indigenous Medicine, University of Colombo. Preservatives or buffering agents were not added to the final preparation.

Table 01 - Ingredients of *Haridradi Ashcyotana* (HA) [7,8,9,10,11,12]

Ingredients	Family	Local name	Sanskrit name	Part used
Terminalia chebula Retz.	*Combretaceae*	*Aralu*	*Haritaki*	Fruits
Terminalia belerica (Gaertn.) Roxb.	*Combretaceae*	*Bulu*	*Bibhitaka*	Fruits
Phyllanthus emblica L.	*Euphorbiaceae*	*Nelli*	*Amalaki*	Fruits
Curcuma longa L.	*Zingiberaceae*	*Kaha*	*Haridra*	Tender Leaves
Coscinium fenestratum (Gaertn.) Colebr.	*Menispermaceae*	*Weniwel*	*Kaliyaka*	Stembark
Pterocarpus santalinus L. f.	*Fabaceae*	*Rat handun*	*Rakta candana*	Bark
Glycyrrhiza glabra L.	*Fabaceae*	*Welmi*	*Madhuyashtika*	Root

Method of preparation of HA[7]

The 07 (seven) herbal ingredients were measured in equal amounts as 25.75 g each and made into *Yavakuta* form (coarse powder/ size of barley grain) and washed thoroughly with pure water. The ingredients were put into a clean sterile new clay pot prepared prior to the preparation. Then added 6 bottles (750*6= 4500mL) (4.5 L) of clean filtered water and the decoction was prepared by simmering to 1/6 (750mL) in mild temperature (85^0-$90\ ^0$C). The final decoction was filtered twenty-one (21) times under sterile conditions, through a minute pore diameter (tightly woven) sterile cotton cloth. Then ¼ bottle (187.5mL) of genuine bee honey was added to the filtrate, when the decoction was cooled in room temperature. The final preparation was re-filtered with a sterile fine cloth. Every 10mL of the filtrate was introduced to sterile glass dropper bottles and labelled accordingly with the prepared date and stored in a cool dry place without exposure to direct sunlight.

Analysis of bee honey[13]

Analysis of bee honey was done at chemical and microbiological laboratory of Industrial Technology Institute, Colombo 07, Sri Lanka. The following tests were done to identify genuine bee honey.

- Fiehe's test (Hydroxymethylfurfural test- Qualitative test) - According to Sri Lanka standard specification intended for bee honey SLS 464:1979
- Microscopy: presence /absence of different types of pollen grains indicating various source plants
- Physico- chemical specifications of bee honey - According to Sri Lanka standard specification intended for bee honey (SLS 464:1979). Reducing sugar, sucrose, glucose – fructose ratio, acidity as formic acid, total ash and moisture were analysed

Quality assessment of HA[13,14,15,16, 17]

HA was standardized at Herbal Technology Division, Industrial Technology Institute, Colombo 07, Sri Lanka to assess the quality and the safety of the end preparation. The following Quality control parameters were assessed.

- Thin Layer Chromatography (TLC) fingerprint.

- Phytochemical screening was done to determine the presence/absence of alkaloids, saponins, steroid glycosides, tannins and flavonoids.
- Microbiological limits were screened to determine the presence/absence of Staphylococcus *aureus*, Coliforms, *Escherichia coli* and *Pseudomonas aeruginosa*.

Analysis of bee honey and the Quality assessment of HA are mentioned under the results section.

The Clinical study

Ethical consideration : The Ethical approval was obtained from the Institutional Ethics Review Committee (Approval number: ERC 14/17) prior to undertaking the clinical study. The study was done in compliance of clinical research guidelines [Good clinical practices (Sri Lanka), Declaration of Helsinki (2013), Standards and Operational guidance for ethics review of Health- related research with human participants (2011)[18]

Study design and study setting

Single arm clinical study was conducted in the Out Patient Department of *Shalakya* clinic of National Ayurveda Teaching Hospital, Borella, Sri Lanka.

Sample size and sampling technique

The sample size was 20 patients and consecutive convenience sampling method was used.

Criteria for selection of patients

Inclusion criteria:

- Patients with signs and symptoms of *Abhishyanda* and clinical diagnosis of Bacterial conjunctivitis in one or both eyes.
- Patients of any race, either gender, age between 10 – 70 years.
- Able to understand and sign the informed written consent. If the subject was a minor, it was signed by parents or legal guardian.
- Patients willing to comply with study visit schedules, photographs and other study requirements.

Exclusion criteria:

- Patients below 10 years and above 70 years.
- Patients with any serious or debilitating systemic disease/s, complicating factors that would negatively affect the conduct or the outcome of the study.
- Lid disease/s or other serious ocular diseases other than Bacterial conjunctivitis.
- Suspected viral or allergic conjunctivitis.
- Using of other topical or internal ocular medication.
- Pregnant or lactating women

Registration and enrollment of trial participants: The data were generated using an elaborative research questionnaire which was specially designed to incorporate the general information, diagnostic parameters, conjunctival smear culture analysis, digital photography, safety assessment and the global efficacy of the registered patients. Diagnostic criteria/ study parameters along with a grading system for the criteria were included to record and assess the clinical parameters accurately in the baseline enrollment and during entire study visits (Table 02).

Table 02- Grading system of the study parameters of *Abhishyanda* w.s.r. Bacterial conjunctivitis

Study parameter/s	Grading	Criteria
Matting of the eye lids	None - 0	No manifestation
	Mild - 1	Slight matting in the morning
	Moderate - 2	Marked matting in the morning
	Severe - 3	Marked matting throughout the day
Conjunctival discharge	None - 0	No manifestation
	Mild - 1	Wipes the eye/s 2-3 times per day

	Moderate - 2	Wipes the eye/ eyes 7-8 times per day
	Severe - 3	Wipes the eye/s more than 10 times per day
Bulbar conjunctival injection	None - 0	No manifestation
	Mild - 1	Dilatation of several vessels
	Moderate - 2	Dilatation of many vessels
	Severe - 3	Impossible to distinguish individual blood vessels
Palpebral conjunc-tival injection	None - 0	No manifestation
	Mild - 1	Dilatation of several vessels
	Moderate - 2	Dilatation of many vessels
	Severe - 3	Impossible to distinguish individual blood vessels
Foreign body sen-sation	None - 0	No manifestation
	Mild - 1	Sometimes there is irritation.
	Moderate - 2	More frequently irritation is present
	Severe - 3	Always irritation is present
Chemosis	None - 0	No manifestation
	Mild - 1	Partial conjunctival swelling
	Moderate - 2	Diffuse thin chemosis
	Severe - 3	Marked swelling of the conjunctiva
Photophobia	None - 0	No manifestation
	Mild - 1	Slight pain when looking at the light
	Moderate - 2	Difficult to look at light.
	Severe - 3	Cannot look at the light
Itching	None - 0	No manifestation
	Mild - 1	Rarely itching present
	Moderate - 2	Sometimes itching is present
	Severe - 3	Always itching is present
Eye lid swelling	None - 0	No manifestation
	Mild - 1	Localized oedema
	Moderate - 2	Diffuse oedema
	Severe - 3	Diffuse marked oedema
Eye Pain	None - 0	No manifestation
	Mild - 1	Pain on exertion
	Moderate - 2	Pain without exertion
	Severe - 3	Always pain is present with headache
Discomfort	None - 0	No manifestation
	Mild - 1	Patient feels uneasy sometimes
	Moderate - 2	Feels uneasy with exertion
	Severe - 3	Patient feels uneasy always

Laboratory investigations:

Conjunctival smear swab culture

Conjunctival smear swab culture was done in the baseline evaluation and in the end point of study: complete remission of all clinical features of bacterial conjunctivitis for the registered 20 patients. The patients were kept seated with the head tilt little backwards and the material for smear was collected from the lower fornix with the

help of the sterile transport swab and replaced it in the plastic capsule (Fig. 01). The collected all conjunctival smear swabs of the registered 20 patients before and after treatment were handed over to the laboratory immediately for eye swab culture analysis without exposing to the direct sunlight/heat.

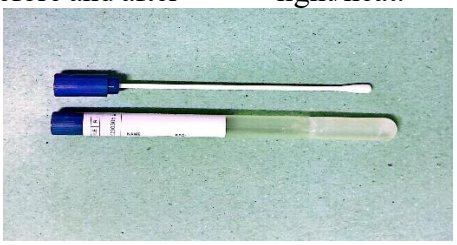

Fig. 01- Transport swab and the plastic capsule

Consent Detail: A written consent was taken from all patients in specially prepared format before trial.

The study procedure

The registered patients were treated with instilling HA approximately 2.5 cm just above the open affected eye/s as two drops three times a day (8 hourly), for ten days under hygienic conditions. Though the time duration was ten days, instilling of eye drop was stopped with subsiding of clinical features of Bacterial conjunctivitis after clinically examining the patient in the clinic. The time duration for remission of the disease was recorded separately. The patients were advised to maintain simple lifestyle modification such as food, water and personal hygiene. The patients were not allowed to take any other prescribed topical or systemic drug/s for similar purpose (Allopathic or Ayurveda) along with research drugs. Patients on medicaments for other systemic diseases were allowed to continue the medicaments after thorough examination, and the details of the drug/s, taken for other systemic disease/s were recorded in a case record format. The patients were free to withdraw from the research while the research was in progress, in any instance.

The Follow up

After dispensing HA on Day 01, the patients were asked to return to the OPD of *Shalakya* clinic of National Ayurveda Teaching Hospital for interim at a one day interval (Day 03, Day 05, Day 07, etc.) for the follow up until the end point of the study. The end point of the study was the clinical and microbial resolution of ocular signs and symptoms as assessed by either subjective or objective parameters with the grading system designed for *Abhishyanda* w.s.r. Bacterial conjunctivitis. Further all the patients were asked to come to the O.P.D. on Day 20 to record the prognosis: complete relief, recurrence or any other feature/s were monitored. During the period of follow up visual acuity, ophthalmoscopy and digital photography were repeated and recorded. The patients were strictly observed for tolerance, developing complications or any adverse effects.

Study assessment variables: Assessed the changes in the mean grades of inflammatory features of *Abhishyanda* w.s.r. Bacterial conjunctivitis before and after treatment with HA, mean days of cure of inflammatory features, the Global efficacy: total days for complete resolution of the disease. Assessed the eye swab cultures before and after treatment with HA. Eye swab culture analysis was used to screen the presence or absence of micro-organisms in eye swabs before and after treatment to evaluate the anti-bacterial activity and the effectiveness of HA. Also, to screen the type of organism/s present in Bacterial conjunctivitis.

Analyzed the exploratory outcome from digital photography before and after the treatment with HA. Photographs were taken in the baseline (Day 01) and end of the study separately for each subject, based on visualized inflammatory features to assess

the anti-inflammatory effect of HA. The constant illumination and the camera settings were maintained, to assure the consistency and the reliability of the photographs. The outcome was objective visual changes based upon a review of the photographs for signs of *Abhishyanda* w.s.r. Bacterial conjunctivitis. The photographs were reviewed before the treatment and after the treatment: at the end of the study and analyzed accordingly. A detailed description of digital photography was included in the questionnaire. Additional beneficial findings of HA were recorded. Safety parameters were evaluated during the study period. Assessed the adverse effects reported by the participants and tolerability of HA. Further the laboratory investigations and standardization of the eye drop were conducted for the safety and acceptability of the herbal trial eye drop. Bee honey was subjected to physico- chemical analysis as adulterants of bee honey are possible in the market samples.

Statistical analysis: Statistical analysis was performed by using the Statistical Package: SPSS version 16. The geographical variables were analyzed by percentage. Inter group statistical analysis for before and after treatment was performed by t-Test: Paired Two Sample for Means. Level of significance was set at $p < 0.05$.

RESULTS

Analysis of bee honey[13]

Fiehe's test (Hydroxymethylfurfural test-Qualitative test) was negative and presence of pollen grains is indicated as genuine bee honey. Physico- chemical specifications of bee honey were within the permissible range. These specifications proved that the used bees honey was genuine and suitable to use in eye drop preparations.

Quality control parameters of the HA

Thin Layer Chromatography (TLC) fingerprint: The R_f values of the prominent spots under UV light (at 254 nm and 366 nm) were 0.03, 0.15, 0.27, 0.44, 0.45, 0.63, 0.70, 0.86. R_f values and colours of the prominent spots after spraying vanillin sulphate were 0.25 (Orange), 0.44 (Brown**),** **0**.51 (Purple)[13].

Fig. 02- R_f values of the prominent spots 254nm

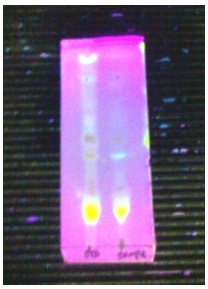

Fig. 03- R_f values of the prominent spots 366nm

TLC fingerprint of HA ensured consistent quality of the product. TLC fingerprint profile of the eye drop consists of 8 prominent spots. R_f values of the prominent spots under UV light (at 254 nm and 366 nm) and after spraying vanillin sulphate[13].

Phytochemical screening: Alkaloids, saponins, steroidal glycosides, tannins and flavonoids were the secondary metabolites present. Phytochemicals are secondary metabolites produced by plants to overcome environmental stress, hence it was used to cure the inflammatory condition of Bacterial conjunctivitis[13].

Microbiological Limits: Microbial evaluation revealed the absence of *Staphylococcus aureus*, *Pseudomonas aeruginosa*, Coliforms and *Escherichia*. Thus, provided evidence as a pathogen free safe sterile eye drop throughout the period of use[13].

Clinical study variables

Registered 20 patients were treated with instilling HA and observations and results were drawn from the completed 20 patients.

a. Conjunctival swab culture

Laboratory analysis of conjunctival smear swab culture of the registered 20 patients for the presence or absence of micro - organisms before and after treatment with the trial eye drop is tabulated in Table 03.

Table 03 - Analysis of conjunctival swab culture for the presence or absence of micro-organisms before and after treatment of the 20 registered patients.

Organism/s	Number of conjunctival smear swabs	BT	AT	Percentage of microbiological remission
Staphylococcus aureus	7	+	-	100.0%
Escherichia coli	4	+	-	100.0%
Staphylococcus aureus + Escherichia coli	5	+	-	100.0%
*No organisms found in the culture	4	-	-	*no organisms found before and after the treatment

BT: Before treatment AT: After treatment (+): Present (-): Absent

The laboratory culture reports showed variations on the presence and absence of micro-organisms in the conjunctival smear swabs before treating with HA. Seven conjunctival smear swabs were positive with *Staphylococcus aureus* and four swabs were positive with *Escherichia coli* while five swabs were positive with both *Staphylococcus aureus* and *Escherichia coli.* Four conjunctival smear swabs were negative of any micro- organism before treating with HA. After treating with HA all the conjunctival smear swabs were negative for organisms including the swabs which were positive of organisms prior to instilling the trial eye drop.

Exploratory outcome from digital photography

Digital photography indicated features of inflammation such as redness, swelling and excessive lacrimal secretions of the eye/s before treating with HA and after the treatment on day 4 indicated absence of all so mentioned features in Fig.04 (a) & (b). Inflammatory features of the eye before treating with HA and after the treatment on day 5 indicated absence of all inflammatory features in Fig.05 (a) & (b).

(a) (b)

Fig.04 - Photographs taken (a) before and (b) after treatment with HA on day 4

(a) (b)

Fig.05 - Photographs taken (a) before and (b) after treatment with HA on day 5

Exploratory outcome from digital photography proved the absence of inflammatory features of Bacterial conjunctivitis after treating with HA.

Clinical profile

Study parameters of Bacterial conjunctivitis

Presenting complaints/ inflammatory features (study parameters) of Bacterial conjunctivitis were recorded from the total registered patients and it was analyzed (Table 04).

Table 04- Inflammatory features (study parameters) presented among the Bacterial conjunctivitis patients

Inflammatory features of Bacterial conjunctivitis	No. of patients	Percentage
Matting of the eye lids	18	90%
Conjunctival discharge	20	100%
Bulbar conjunctival injection /hyperaemia	20	100%
Palpebral conjunctival injection / hyperaemia	20	100%
Foreign body sensation	14	70%
Chemosis	17	85%
Photophobia	17	85%
Itching	16	80%
Lid swelling	11	55%
Eye pain	8	40%
Discomfort	20	100%

The highest frequencies (n=20) of clinical features presented were Bulbar conjunctival hyperaemia, Palpebral conjunctival hyperaemia, conjunctival discharge and discomfort. The 2nd highest frequency was matting of lids (n = 18) and the lowest was eye pain (n=08).

The assessment of mean grades /scores of inflammatory features of Bacterial conjunctivitis

The mean grades /scores of inflammatory features of Bacterial conjunctivitis before and after treatment with HA are shown in Table 05.

Table 05 - Mean grades of clinical parameters before and after treating with HA

Clinical Parameters	n	Mean Grade		SD	SE	t	p
		BT	AT				
Matting of eye lids	18	2.00	0.00	0.91	0.21	9.35	2.05E-08**

Conjunctival discharge	20	2.20	0.00	0.77	0.17	12.81	4.24E-11**
Bulbar conjunctival hyperaemia/injection	20	2.55	0.00	0.61	0.14	18.86	4.63E-14**
Palpebral conjunctival hyperaemia/injection	20	2.45	0.00	0.76	0.17	14.43	5.41E-12**
Foreign body sensation	14	2.14	0.00	0.86	0.23	9.28	2.14E-07**
Chemosis	17	2.41	0.00	0.62	0.15	16.08	1.34E-11**
Photophobia	17	2.24	0.00	0.90	0.22	10.20	1.04E-08**
Itching	16	2.38	0.00	0.89	0.22	10.73	9.77E-09**
Lid swelling	11	1.73	0.00	0.65	0.20	8.86	2.38E-06**
Pain	8	1.75	0.00	0.71	0.25	7.00	1.06E- 03**
Discomfort	20	2.00	0.00	0.86	0.19	10.42	1.35E-09**

N: Number of study units BT: Before treatment AT: After treatment SD: Standard Deviation SE: Standard error *p < 0.05: Significant ** p < 0.001: Highly significant

Mean days of cure of inflammatory features of Bacterial conjunctivitis

Analysis of the mean days of cure of inflammatory features are shown in Fig. 06.

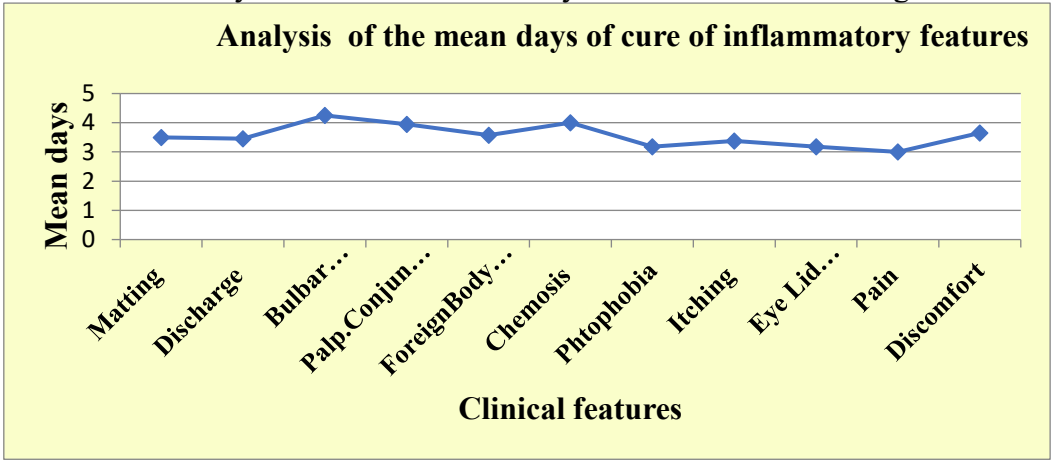

Fig. 06 - Mean days of cure of inflammatory features

The mean days of remission in all clinical parameters in patients treated with HA is between day 2.5 – 4.5.

Global efficacy: The total days for the complete cure of Bacterial conjunctivitis with HA is tabulated in Table 06.

Table 06 - Global efficacy: Total days for complete cure with HA

Patient serial number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Total days for the com-pletee cure	5	4	3	7	5	3	3	5	5	5	5	5	3	5	5	3	5	5	5	3
Mean days = 4.45																				
Days for cure range = 3 - 7 days																				

The days for complete resolution of the disease in patients were scattered while the mean days for Global efficacy / total days for the complete cure of Bacterial conjunctivitis was 4.45 with HA. The disease was cured within the range of 3-7 days maximum with HA.

Safety assessment: The presence/ absence of adverse effects, visual disturbances and eye pathologies and the tolerability by instilling HA are tabulated in Table 07.

Table 07 – The safety assessment and the tolerability of HA during the clinical trial

Safety criteria	Observation/Percentage
Eye irritation	0%
Development of adverse effect/s	0%
Visual disturbances	0%
Eye pathologies and abnormal ophthalmoscopic findings	0%
Tolerability	Good

DISCUSSION: In the present study the patients in the age range of 10-70 yrs. were treated with *Haridradi Ashcyotana* to evaluate the efficacy and the safety in the management of *Abhishyan*da w.s.r. to Bacterial conjunctivitis. Standardization parameters as analysis of bee honey, TLC fingerprint, microbial assessment and phytochemical screening of HA ensure consistent quality of the product with the presence of original herbal ingredients in the final preparation. Thus, the quality assessment parameters can be used to address the safety, consistency and effectiveness of HA. Conjunctival smear swabs were negative for *Staphylococcus aureus* and *Escherichia coli* after instilling with the trial eye drop which gives evidence that HA was responsible for 100% bacterial remission possessing the anti-bacterial effect against *Staphylococcus aureus* and Escherichia *coli.* Exploratory outcomes from digital photography proved the absence of inflammatory features of Bacterial conjunctivitis after treating with HA which revealed the anti-inflammatory potentials with complete clinical remission. Hence, HA was effective in complete remission of clinical spectra and bacterial eradication of *Abhishyanda* w.s.r. to Bacterial conjunctivitis. The correct treatment will alleviate the vitiated *Dosha* and will not produce other diseases, and it will not produce a disease while curing the disease[19]. HA showed highly significant results ($p < 0.001$) on remission of all inflammatory features with a 100% response rate. The overall effects of HA were evaluated by considering mean grades of inflammatory features before and after treatment with HA and analyzing the significance by the 'p' values. The matting of eye lids ('p' value: 2.05E-08), conjunctival discharge ('p' value: 4.24E-11), bulbar conjunctival hyperaemia ('p' value: 4.63E-14), palpebral conjunctival hyperaemia ('p' value: 5.41E-12), foreign body sensation ('p' value: 2.14E-07), pain ('p' value: 1.06E- 03) and discomfort ('p' value: 1.35E-09) showed highly significant results ($P < 0.001$) with resolving all mentioned inflammatory features. SD values were not deviated from the mean, hence the data were more confident and predictable.

The total mean days were 4.45 for the resolution of the disease while the range for total cure days with HA were 3-7 days which was not deviated from the total mean days for cure, thus proved as a promising herbal

ophthalmic preparation. Treatment of patients with bacterial conjunctivitis should be well tolerated when instilled into the eye[20]. There were no side effects observed (0%) during the entire study (Table 07) and HA was well tolerated by the patients. No drug related effects were observed on visual acuity, ophthalmoscopic findings or eye/s during the entire study. Herbal medicines are generally regarded as safe based on the long-standing use in various cultures [6]. Hence, Quality control parameters of the eye drop and clinical study variables were utilized for scientific validation of a Sri Lankan Traditional medicinal herbal eye drop.

CONCLUSION

Haridradi Ashcyotana is safe, tolerable, quick action and effective ophthalmic preparation in the management of *Abhishyanda* w.s.r. to Bacterial conjunctivitis with the anti-inflammatory and anti-bacterial potentials to overcome the current issues in primary health care sector in controlling of infectious eye diseases. Thus, can be concluded as *Haridradi Ashcyotana* is a sterile, effective and safe herbal ophthalmic preparation in the management of *Abhishyanda* with special reference to Bacterial conjunctivitis.

DECLERATION

We have not used any AI or AI based tools for the preparation of manuscript. AI or AI based contents are not published.

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