

EFFICACY OF *TRIPHALA PARISHEKA* IN THE MANAGEMENT OF *AMAJA NETRA ROGA* (ACUTE CONJUNCTIVITIS) : A CONTROLLED CLINICAL TRIAL

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Abstract: BACKGROUND: *Shalaky Tantra* is one of the branches of *Astanga Ayurveda* and *Netra Roga Vigyana* is its sub division. According to *Yogaratanakara (Netra Rogadhikara)* specially mentioned, type of eye disease based on *Ama* and *Nirama* aspect of eyeball. Which is *Ama Awastha* in *Netra Roga* and *Nirama Awastha* in *Netra Roga*. According to *Yogaratanakara* characterized by *Udirna Vedana*, (Pricking pain) *Ragata* (Redness of eye) *Shopa* (Swelling of eye lid) *Garshana* (FB sensation) *Toda* (Intense pain) *Shoola* (Pain) *Ashru Srava* (Watering of eye) *Daha* (Burning sensation) *Netra Gaurava* (Heaviness of eyes). AIM: To compare the efficacy of *Triphala Parisheka* and Moxifloxacin eye drops in the Management of *Amaja Netra Roga* (Acute Conjunctivitis). MATERIALS AND METHODS: In this clinical study, total thirty six patients from the Outpatient Department of *Shalaky Tantra* of IPGT and RA, Gujarat Ayurved University, Jamnagar, who were suffering from *Amaja Netra Roga* (Acute conjunctivitis) were registered, out of them all patients completed the treatment. Patients were divided into two groups by simple random sampling method. In Group A *Triphala* decoction *Parisheka* was administered for eye irrigation and, in Group B Administration of Moxifloxacin eye drop for externally. RESULTS: In Group A, 33.33% of patients (6) were cured and, while in Group B, 11.11% of patients (2) were cured. CONCLUSION: The study shows that *Triphala Parisheka* is more effective than Moxifloxacin eye drop in the Management of *Amaja Netra Roga* - Acute Conjunctivitis. .

Key Words: *Amaja Netra Roga*, Acute conjunctivitis, *Triphala Parisheka*.

1. INTRODUCTION:

Conjunctivitis is the inflammation of the conjunctiva, which is the clear membrane covering the sclera (white part of the eye) and interior lining of eyelids. It has worldwide distribution, affecting persons of all ages, races, social status and both genders. It was found approximately 35% of all eye-related problems and mostly seen in summer season and affecting poor hygienic people predominantly.¹

Conjunctivitis can be divided into Infectious and Non Infectious due to causes. Virus and Bacteria are the most common infectious causes. Noninfectious conjunctivitis includes Allergic, Toxic and Cicatricial etc. The disease can also be classified into Acute, Hyper acute and Chronic according to the mode of onset and the severity of the clinical response. Viral conjunctivitis is the most common cause of infectious conjunctivitis, more prevalent in summer in the Adult population. Bacterial Conjunctivitis is the second most common cause and is responsible for the majority of cases in Children. In this disease, common clinical features are, Redness of eye (sudden onset), unilateral or bilateral discharge (muco-purulent or watery), Irritation, Burning and FB sensation, Grittiness, Blurred vision, Mild photophobia, Sticking together of lid margins and slightly edematous lids.² On the basis of similar clinical features Conjunctivitis (Acute) can be co-related with the disease of *Amaja Netra Roga* which has been described under the context of *Netrarogadhikara* in *Yogaratanakara*.³

Acute Conjunctivitis is curable as per modern view management with Antibiotics and NSAIDs, but leads to suppression of immunity. As a result, the recurrence rate is high.⁴ Its prevalence rate is very high and commonly seen in ophthalmological disorders.

Triphala pacifies the *Tridoshas* and is a potent astringent with Anti Inflammatory, Homeostatic and Wound healing properties. It is beneficial in the disease of eye, due to properties of *Chakshushya*, *Rasayana*, *Shothahara* and *Deepana*. *Triphala* decoction is easy to made and cost effective drug in Ayurvedic management. *Acharya Chakradatta*

clearly mentioned six measures (*Swedana, Pralepa, Tikta Anna, Netra Seka or Parisheka, Langhana and Pachana*) in the management of acute stage of eye disease (*Amavastha of Netraroga*).⁵ Though previous study have been conducted with significant result on efficacy of *Parisheka* in Acute Conjunctivitis (*Amaja Netra Roga*), but no comparative study has been carried out between *Ayurveda* and Modern drug modalities.

So, the study was planned to find out an effective Ayurvedic management for *Amaja Netra Roga* (Acute conjunctivitis) with *Triphala Kwatha Parisheka*.

2. AIMS AND OBJECTIVES:

- To evaluate the efficacy of *Triphala Parisheka* in the Management of *Amaja Netra Roga* (Acute Conjunctivitis).
- To compare the efficacy of *Triphala Parisheka* and Moxifloxacin eye drops in the Management of *Amaja Netra Roga* (Acute Conjunctivitis).

3. MATERIALS AND METHODS:

Study design - In this clinical study, total thirty six patients from the Outpatient Department of *Shalaky Tantra* of IPGT and RA, Gujarat Ayurved University, Jamnagar, who were suffering from *Amaja Netra Roga* (Acute conjunctivitis) and fulfilling the criteria of inclusion for the present study, were registered, out of them all patients completed the treatment. An elaborative research pro forma was specially designed for the purpose of incorporating all aspects of the disease on *Ayurvedic* and modern aspect. Clinical study was started after getting clearance from the Institutional Ethics Committee (No. PGT/7/-A/Ethics/2017-18/2097-Dated 24/11/17), and the study was also registered under the Clinical Trial Registry of India (CTRI/2017/12/011018 - Dated 28-12-2017). Informed consent was taken from the patients. Selected patients were randomly divided into two groups.

Criteria for inclusion:

- Patient of either sex aged between 18 to 50 years.
- Patients presenting with signs and symptoms of *Aamavastha of Netra Roga* (Acute conjunctival inflammation) described as per *Ayurveda* and Modern science.
- Willing and able to participate in the study.

Criteria for exclusion:

- Patient below 18 and more than 50 years of age.
- Patients not willing for attending the hospital for the procedures daily and registration.
- Complicated Conjunctivitis with Glaucoma, Uveitis, Corneal Ulcer, Panophthalmitis, Dacryocystitis, Episcleritis and Ocular trauma.
- Patients presenting after 7 days of ocular complaints.
- Special type of conjunctivitis - Kerato conjunctivitis, Allergic conjunctivitis, Trachoma
- Any systemic disorder which may alter the result of the study (uncontrolled diabetes mellitus and hypertension).

ADR: No adverse drug reactions were obtained during as well as follow up period of clinical trial in the patients of both the groups.

Investigation:

Laboratory investigations were carried out before treatment to rule out any pathological conditions.

1. Hematological Examinations: Hb%, TC, DC, ESR
2. Biochemical Examinations : FBS (Fasting Blood Sugar)

Grouping:

Patients were divided into two groups by simple random sampling method. In Group A *Triphala* decoction *Parisheka* was administered for eye irrigation and, in Group B Administration of Moxifloxacin eye drop for externally.

1. Group A – *Seka* (Irrigation of eyes) with *Triphala Parisheka*. A total of 18 patients were administered with *Triphala* decoction around the closed eyes as per developed SOP three times a day for seven days.
2. Group B – Moxifloxacin eye drop. A total of 18 patients were administered with moxifloxacin eye drops topically three times a day, one drop in each eye for seven days.

Follow up – After completion of the trial patients will be managed further till asymptomatic phase and followed seven more days for any recurrence of the symptoms.

Pathyapathya – Advised *Laghu Ahara* (light food) when he/she gets hunger and *Matra* to be half of his/her hunger. To follow *Samyak Nidracharya* and advised to avoid *Divaswapna*. Advise take proper rest. Avoid direct sun light, dust wind and smoke. Wear black goggles. (In both groups were given advice to take Light diet and maintain proper hygiene.)

4. CRITERIA FOR ASSESSMENT:

Assessment was done on the basis of improvement in clinical features. Subjective and objective parameters of the patients before and after treatment by using a standardized grading scale as per the WHO guidelines for Clinical Research Methodology in *Ayurveda* developed by I.P.G.T & R.A, Jamnagar, the details are given as follows:

Subjective criteria:

1. *Udirna Vedana*, – Pain in the Eyes

No Pain	0
Pain not hampering the Routing work	1
Pain the disturbs /hampering the routing work	2
Severe Pain where patients unable to perform routing work	3

2. *Gharsana* – Foreign Body Sensation

No Foreign Body Sensation	0
Occasional Foreign Body Sensation	1
Frequent Foreign Body Sensation	2
Continuous Foreign Body Sensation	3

3. *Daha* - Burning Sensation

No Burning Sensation	0
Mild Burning Sensation	1
Moderate Burning Sensation	2
Severe Burning Sensation	3

4. *Netra Gaurava* - Heaviness in eyes

No Heaviness	0
Mild Heaviness	1
Moderate Heaviness	2
Severe Heaviness	3

5. *Sirah Shula* (Headache)

No Headache	0
Mild Headache	1
Moderate Headache	2
Severe Headache	3

Objective criteria:

1. *Ragata* – Redness/Congestions of Conjunctiva (Palpebral, Bulbar and Fornixes)

No Congestion	0
Mild Congestion (Congestion with clear pattern of blood vessels)	1
Moderate Congestion (Congestion with poorly visible pattern of blood vessel)	2
Severe Congestion (Completely obscuring the pattern of blood vessels)	3

2. *Shopa* – Swelling of eye lids

No Swelling	0
Slight Swelling	1

Moderate Swelling with partial eversion of lids	2
Swelling with lids more than half closed	3

3. Asru Srava – Watering / Lacrimation

No excessive Lacrimation	0
Lacrimation only during exposure to sunlight	1
Continuous Lacrimation throughout the day time	2
Continuous Lacrimation throughout the day and night	3

4. Pichcila Srava – Mucoïd Discharge

No mucous discharge	0
Discharge not requiring mopping (Mild discharge)	1
Discharge requiring intermittent mopping (Moderate discharge)	2
Discharge causing sticking of eyelashes (Copious discharge)	3

Statistical analysis

Student’s paired *t*-test was applied to access the results for individual groups, and unpaired *t*-test was used to calculate the comparison of results between the groups. The results were interpreted at the level of $P < 0.001$ as highly significant, $P < 0.05$ as significant, and $P > 0.05$ as insignificant.

5. RESULTS AND OBSERVATIONS:

Total 36 patients were registered for this clinical study (18 patients in Group A and in 18 patients in Group B). Among them 18 patients in Group A and 18 patients in Group B registered and completed in both the group equally. No any drop out patients was found in this study. So, Demographic and clinical data have been presented for 36 patients (under observations and results) are given below.

Demographic profile - It was observed that majority of the patients, i.e., 33.33% were reported in the age group of 18-30 years, maximum, i.e. 66.7% of patients were male, maximum, i.e., 83% of patients were Hindus, maximum, i.e., 46.1% of patients were labor, maximum, i.e., 39% of patients were primary education, majority of the patients registered, i.e., 55.6% belonged to middle class, majority of the patients, i.e., 75% were married, maximum number of patients, i.e., 80.55% belonged to urban area, maximum number of patients, i.e., 75% were vegetarian, maximum, i.e., 75% of patients were addicted to tea, maximum number of patients, i.e., 61.11% had disturbed sleeping pattern, majority of the patients, i.e., 77.80% were having poor appetite, majority of the patients, i.e., 69.44% were had regular bowel habit, majority of the patients, i.e., 47% were having *Pitta Kapha Deha Prakrithi*, maximum number of patients, i.e., 38.99% belonged to *Satva Rajas Manasa Prakrithi*, maximum number of patients, i.e., 89% were having *Madhyama Sara*, maximum, i.e., 52.7% of patients were showing *Mandagni* and maximum number of patients, i.e., 80.6% had *Madhyama Ahara Shakti*.

Clinical profile: The maximum number of patients i.e., 100% of patients had chief complaints of *Ragata* (P.C.) followed by 77.7% were found *Udirna Vedana* and *Ragata* (B.C.). *Gharshana* and *Pichchila Srava* were found in 63.8% of patients. 72.2% of patients had chief complaints of *Daha* (burning sensation), 47.72% of patients had *Shopata* of eyelids and 36.1% of patients had chief complaints of *Ashru Srava* In this study. The maximum number of patients i.e., 33.3% of patients had associated complaints of *Netra Gaurava*, followed by *Sirah Shula* in 25% patients

Effect of therapies on subjective criteria - group A and B: Evaluating the effect of therapy on subjective parameters among the patients in Group A and B, it was found that:

In group A, 83.3% relief was observed in RE and 75.4% in LE on *Udirna Vedana* which was statistically highly significant at the level of $p < 0.001$. In group B, 71.5% relief was observed in RE and 66.6% in LE on *Udirna Vedana* which was statistically highly significant at the level of $p < 0.001$. In group A, 97% relief was observed in RE and 100% in LE on *Gharshana* which was statistically highly significant at the level of $p < 0.001$. In group B, 100% relief was observed in RE and 100% in LE on *Gharshana* which was statistically highly significant at the level of $p < 0.001$. In group A, 80% relief was observed in RE and 75% in LE on *Ashru Srava* which was statistically highly significant at the level of $p < 0.001$. In group B, 81.8% relief was observed in RE and 83.3% in LE on *Ashru Srava* which was statistically insignificant at the level of $p > 0.05$. In group A, 100% relief was observed in RE and 100% in LE on *Daha* which was statistically highly significant at the level of $p < 0.001$. In group B, 100% relief was observed in RE and 96.5% in LE on

Daha which was statistically highly significant at the level of $p < 0.001$. In group A, 90% relief was observed in RE and 83.3% in LE on *Netra Gaurava* which was statistically highly significant at the level of $p < 0.001$. In group B, 81.8% relief was observed in RE and 70.8% in LE on *Netra Gaurava* which was statistically significant at the level of $p < 0.05$. In group A, 83.3% relief was observed in RE and 70% in LE on *Shirah Shula* which was statistically significant at the level of $p < 0.05$. In group B, 87.5% relief was observed in RE and 66.6% in LE on *Shirah Shula* which was statistically insignificant at the level of $p > 0.05$.

Effect of therapy on objective parameters - group A and B: Evaluating the effect of therapy on objective parameters among the patients in Group A and B, it was found that:

In group A, 96.6% relief was observed in RE and 86.7% in LE on *Pichchila Srava* which was statistically highly significant at the level of $p < 0.001$. In group B, 100% relief was observed in RE and 100% in LE on *Pichchila Srava* which was statistically highly significant at the level of $p < 0.001$. In group A, 76.4% relief was observed in RE and 86.3% in LE on *Shopa* which was statistically highly significant at the level of $p < 0.001$. In group B, 75% relief was observed in RE and 85% in LE on *Shopa* which was statistically highly significant at the level of $p < 0.001$. In group A, 73.15% relief was observed in RE and 76.4% in LE on *Ragata* (con-P.C.) which was statistically highly significant at the level of $p < 0.001$. In group B, 71.5% relief was observed in RE and 75% in LE on *Ragata* (con-P.C.) which was statistically highly significant at the level of $p < 0.001$. In group A, 90% relief was observed in RE and 96.8% in LE on *Ragata* (con-B.C.) which was statistically highly significant at the level of $p < 0.001$. In group B, 76.6% relief was observed in RE and 83% in LE on *Ragata* (con-B.C.) which was statistically highly significant at the level of $p < 0.001$.

Comparison of effect of therapy- subjective parameters: (right eye and left eye)

In right eye, statistically there is no significant difference between was observed in both groups in all subjective parameters. In left eye, statistically there is no significant difference between was observed in both groups in most of objective parameters, like *Udirna Vedana*, *Gharshana*, *Daha* and *Netra Gaurava*. *Ashru Srava* and *Shirah Shula* was observed in significant difference between in both groups. .

Comparison of effect of therapy - objective parameters: (right eye and left eye)

In right eye statistically there is no significant difference between was observed in both groups in all objective parameters. In left eye statistically there is no significant difference between was observed in both groups in all objective parameters.

Effect of therapy on complaints- Right Eye

- 100% relief was found on symptoms *Daha* in group A, while 98.20% relief was found in group B.
- 90% relief was found on symptoms *Ragata* (B.C.) in group A, while 76.60% relief was found in group B.
- 83.30% relief was found on symptoms *Udirna Vedana* in group A, while 71.50% relief was found in group B (which were highly significant $P < 0.001$)

Effect of therapy on complaints- Left Eye

- 100% relief was found on symptoms *Gharshana* in both the group equally.
- 100% relief was found on symptoms *Daha* in group A, while 96.60% relief was found in group B.
- 97% relief was found on symptoms *Ragata* (B.C.) in group A, while 83% relief was found in group B.
- 90% relief was found on symptoms *Netra Gaurava* in group A, while 70.80% relief was found in group B. (which were highly significant $P < 0.001$)

Overall effect of therapy:

In Group A, 33.33% of patients (6) were cured and, 38.80% of patients (7) were marked improvement, 27.77% patients (5) got moderately improvement. None of the patient got mild improvement or remained unchanged.

In Group B, 11.11% of patients (2) were cured and, 50% of patients (9) were marked improvement, 22.22% patients (4) got moderately improvement. Mild improvement was observed in 16.66 % patients (3) in group B. None of the patient got remained unchanged.

6. DISCUSSION:

Statistically highly significant results were found in Objective parameters in both the groups. Statistically there is no significant difference between two group except *Ashru Srava* and *Netra Gaurava* in subjective parameters in LT eye. In group A most of parameters shows significant change within short duration than group B.

Due to *Kashaya*, *Amla Rasa*, *Laghu*, *Ruksha Guna*, *Ushna Veerya* and *Madhura Vipaka* it is also having Tridodhahara, Deepana and Chakshushya properties. So, it will Pacifies vitiated *Doshas* and enhance proper function of local *Dosha* and *Dhathus*. Finally *Samprapthi Vighatana* and prevention the prognosis of the disease. *Netra Parisheka* which is externally application of medicine on the eye, due to Contact with *Bhrajaka Pitta* (the pitta which is seated in the skin), it will Absorbed through local tissue with the help of *Ushna Ruksha Gunas*. Due to *Pachana* and *Bahirparimarjana* properties of the procedures. *Ama Pachana* will occur and further removes Srotorodha (*Normalization of Sthanika Dhatwagni*) finally it converted to *Amavastha to Niramavastha* of eye. Hence, this formulation was used which can save the time and cost of medicine.

7. CONCLUSION:

Statistically highly significant results were found in all objective parameters and most of subjective parameters in both the groups. Statistically there is no significant difference between two group except *Ashru Srava* and *Netra Gaurava* in subjective parameters in LT eye. So on the basis of overall effect of results it can be concluded, that among the above mentioned line of treatment *Triphala Parisheka* is ideal remedy for the management of *Amaja Netra Roga* (acute conjunctivitis). Because it completely cure almost all sing and symptoms without any adverse effects. During the study, no significant adverse effects were observed. Further studies can be done at large sample size and for long duration to establish the curative effect of both.

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