



A CLINICAL STUDY TO EVALUATE THE EFFICACY OF VIDALAKA KARMA IN THE MANAGEMENT OF PRAKLINNA VARTMA (BLEPHARITIS)

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ABSTRACT

Vidalaka Karma is a *Kriya Kalpa* procedure in which topical application of drugs in the form of paste (*Lepa*) applied over the skin of lids are indicated in inflammatory (*Amavastha*) conditions of the eye lids. *Praklinna Vartma* is a disease of *Vartma* caused by *Kapha Dosha*. In modern science it resembles as blepharitis. The aim of this study was to collect, evaluate and discussed about the mode of action of *Vidalaka Karma* in *Praklinna Vartma*. The desired effect of *Vidalaka Karma* was achieved by using *Vidalaka Yoga* having *Saindhava*, *Daruharidra*, *Gairika*, *Pathya* and *Rasanjana* having *Kapha Dosha Shamaka* qualities. In this study result was found significant in disease *Praklinna Vartma*.

KEYWORDS: *Kriya Kalpa*, *Vidalaka karma*, *Praklinna Vartma*, *Vidalaka Yoga*.

INTRODUCTION

Kriyakalpa is well known therapeutic process in Shalakya Tantra, as the Panchkarma. Aschyotana, Seka, Vidalaka, Pindi, Tarpana, Putapaka, and Anjana are different Kriyakalpas in Ayurvedic classics.^[1] In successive order first four procedures (Aschyotana, Seka, Bidalaka, Pindi) used in Amavastha (acute eye condition) and Tarpana, Putapaka, Anjana used in Niramavastha (after subside of acute features).^[2] Kriyakalpa has several advantages over oral administration like they are not metabolized systemically, probably will rectify accumulated Doshas locally in less time. Many oral drugs have difficult to cross blood aqueous, blood vitreous and blood retinal barrier to reach target tissue. The topical drug made considering anatomy and physiology of ocular tissue can reach there and achieve higher bioavailability. Vidalaka Karma is a procedure comes under Bhirparimarjana Chikitsa. It is a form of Lepa Kalpana (Doshaghna) and the thickness is 1/4 Angula (apx.4.7mm).^[3] This was applied over the lid excepting the eyelashes in lid disease Praklinna Vartma. Praklinna Vartma is Kapha Dosha Pradhana Sadhya Vyadhi.^[4] It has similarities with blepharitis. Blepharitis is a subacute or chronic inflammation of the lid margins.^[5] Ulcerative and non-ulcerative inflammation of hair follicles and glands along the edges of the eyelids.^[6] High recurrence rate make blepharitis difficult to manage.^[7]

NEED OF THE STUDY

There are several treatment given for *Praklinna Vartma* in *Ayurvedic classics*; all have good effect but to know the effect *Kriyakalpa*, to minimize the recurrence of the disease and to achieve the maximum efficacy of the treatment, *Vidalaka Karma* had been planned. It is less irritant, easily applicable and equally efficacious like other treatment.

AIM AND OBJECTIVES

1. To evaluate the efficacy of '*Vidalaka Yoga*' in the management *Praklinna Vartma*.
2. To assess the efficacy of '*Vidalaka Karma*' in the management of *Praklinna Vartma*.

MATERIALS AND METHODS

Clinical study was carried out in three phases

- (1) Diagnostic phase.
- (2) Interventional phase.
- (3) Assessment phase.

A) Diagnostic phase

1. Criteria for selection

a) Selection of the Disease

Praklinna Vartma is a very common and chronic disease. It is Kapha Pradhana Vyadhi which involve the Netra Vartma (eyelid) and causes the vitiation of Rakta, Mamsa and Twaka Dhatu.

b) Selection of the Patients

Patients presenting with clinical features of *Praklinna Vartma* - Blepharitis was selected from the OPD & IPD of P.G. Dept. of Shalakya Tantra; Rishikul Campus Haridwar.

c) Selection of the Drug

Because of easy process, high bioavailability, less time requirement *Vidalaka Kriya Kalpa* procedure taken, this is useful in chronic condition of diseases where long term acting drugs are needed. The *Dravya* [drugs] of *Vidalaka Yoga* (*Saindhava*, *Daruharidra*, *Gairika*, *Pathya* and *Rasanjana*) having *Kapha Shamaka* properties. After proper identification it was collected from local market in Haridwar and prepared properly in *Rasashastra* Department of Rishikul Campus Haridwar.

2. Criteria of Inclusion

- Patient presenting with sign and symptoms of *Praklinna Vartma* and Blepharitis.
- Patient willing to participate
- Age – 7yr -70yr.
- Sex – either sex.

3. Exclusion Criteria

- Patients having diseases like Ectropion, Entropion, Trichiasis, Lagophthalmous, Acute/chronic infective conjunctivitis Corneal ulcer, Dacryocystitis, Dry eye, etc.
- Patients suffering from specific eye lid disorders like Tumor, Carcinoma, Skin allergies.
- Systemic diseases like- DM, HTN.

4. Criteria for Withdrawal

1. If any serious condition or any serious adverse effects appear during the course of study which requires urgent treatment.
2. If patient wants to withdraw him/herself from the clinical study.

5. Criteria for Diagnosis

All the patient of *Praklinna Vartma* (Blepharitis) was diagnosed on the basis of various clinical presentation, laboratory investigation and findings.

Subjective Parameters

1. *Arujama* (*Alparujam*) or *Nishtoda* (Pain at lids).
2. *Kandu* (Itching at lids).
3. Burning sensation at lids.

Objective Parameters

1. *Bahyataha Shunama* (Lid oedema).
2. *Antah Klinnta* or *Srava* (Sticky discharge at lid margins).
3. Scaling at lid margins.
4. Falling of eye lashes.
5. Meibomian gland expression.
6. Conjunctival scarring.

Functional Examination of Eyes

External Examination, visual acuity, Slit lamp examination, Fundoscopy.

Investigations

Routine Hematology.

- Blood sugar (Fasting and PP).
- Erythrocyte sedimentation rate (ESR).
- Complete blood count.

B) Interventional phase**Study design**

The method adopted for the study was open randomized clinical study.

Sampling

A total number of 15 patients with signs and symptoms of *Praklinna Vartma* (Blepharitis) was registered and treated with *Vidalaka Karma* one time/ day (till dry) up to 15 days.

Plan of work

The study was carried out as follows

Proforma

A special proforma was prepared on the basis of signs and symptoms of *Praklinna Vartma* and Blepharitis described in *Ayurvedic* and modern text respectively to maintain the records of all findings (before and after treatment) regarding the patients.

Informed Consent

The purpose of the study, nature of the study, the procedure to be carried out and the potential risk and benefits were explained to the patients in detail in non-technical terms and trilingual. Thereafter written informed consent was taken from each patient before starting the study.

Diet Recommendation

Patients were advised to follow *Pathya Ahara* and *Vihara* as mentioned in *Netra Roga Chikitsa* in classics before and after the treatment.

Vidalaka Karma (Procedure)**1. Purva Karma****a) Preparation of Vidalaka Yoga**

Fine powder of all 5 content which was made properly and made like a paste with Luke warm water.

b) Collection of Instruments

All instruments which are useful for procedure collected before the therapy.

c) Preparation of Patient**Selection of Patient**

Patient was selected after proper examination (*Roga* and *Rogi Priksha*) having sign and symptoms of disease.

Position of Patient

Patient was made to Supine position on *Kriya Kalpa* table.

Cleaning of eyes and face

Wiping/ cleaning the skin of lids, orbital area with whole face by sterile cotton swab done before *Vidalaka Karma*.

Snehana and Swedana

Before starting the procedure *Mridu Snehana/ Abhyanga* followed by *Swedana* was applied on face and lids to relax the patient and increase the vasodilation of local area.

2. Pradhana Karma (Procedure)

Patients were advised to close the eyes and *Vidalaka* procedure was performed in the closed eyes. Paste was applied all around the eyelids in a circle uniformly except lid margins.

Temperature

Temperature of *Vidalaka Lepa* was used *Sukhoshna*.

Duration of Performing Vidalaka Karma

Duration of the procedure at one sitting was approximately 10-15 minute (till dry).

Vidalaka Karma performed in a day

One time /day.

Complications

No complication of the procedure was noticed.

3. Paschgata Karma

Wiping/ cleaning the skin of lids and orbital area with cotton swab and luke warm water after *Vidalaka Karma*.

Contraindications

- Excessive speaking, jokes, anger, grief, weeping etc.
- Wandering under the sun.
- Day sleep.

Otherwise they may produce itching/dryness of the skin, *Peenasa* and disturb vision.

C) ASSESSMENT PHASE**Criteria for assessment**

Most of the signs and symptoms of *Praklinna Vartma* and *Blepharitis* described in *Ayurveda* are subjective in nature, to give the results objectively and for statistical analysis multidimensional scoring system have been adopted. Score was given according to severity of symptoms. Assessment was done on the basis of clinical feature of the patient before and after treatment by following the scoring pattern.

1) Arujam/ Alparujam or Nishtoda (Severity of pain)

- 0 No pain.
- 1 Occasional pain.
- 2 Persistent do not disturb routine work.

- 3 Disturb routine work.

2) Kandū (Itching at lid margins)

- 0 No itching.
- 1 Occasional itching.
- 2 Persistent do not disturb routine work.
- 3 Disturb routine work.

3) Burning sensation at lids and eye

- 0 No burning sensation.
- 1 Occasional burning sensation.
- 2 Persistent do not disturb routine work.
- 3 Disturb routine work.

4) Bahyataha Shunama (Lid oedema)

- 0 No oedema.
- 1 Slightly narrowed palpebral fissure (3/4 of normal width) with congestion.
- 2 Narrowed palpebral fissure with oedema (2/3 of normal width).
- 3 Narrowed fissure with severe oedema (1/3 of normal width).
- 4 Massive oedema (cornea barely visible).

5) Antaha Klinnata or Srava (Discharge at lid margins)

- 0 Mating of eye lashes absent.
- 1 Mating of 2-4 eye lashes.
- 2 Mating of 5-7 eye lashes.
- 3 Mating of 8-10 eye lashes.

6) Scaling

- 0 No Scale.
- 1 1-5 Scales.
- 2 6-10 Scales.
- 3 > 10 Scales.

7) Falling of eye lashes

- 0 No fall of eye lashes.
- 1 Falling of 1/3rd of total eye lashes.
- 2 Falling of 2/3rd of total eye lashes.
- 3 Falling of > 2/3rd of total eye lashes.

8) Conjunctival scarring

- 0 No conjunctival scarring.
- 1 Arlt's line conjunctival scarring.
- 2 Discrete conjunctival scarring.
- 3 Lid deformity scarring.

9) Meibomian gland expression

- 0 Normal, Clear, may have a few particle.
- 1 Opaque with normal viscosity.
- 2 Opaque with increased viscosity.
- 3 Severe thickening (Toothpaste like).

Statistical Analysis

The information regarding demographic data was given in percentage. The data obtained in clinical study is subjected to statistical tests and analyzed. **Wilcoxon's signed rank test (W- value)** was applied to evaluate %

relief before and after treatment in each group and finally result were incorporated in terms of Probability (P).

OBSERVATIONS AND RESULTS

Out of all 15 subjects registered for the present study 53.3% were female and 46.7% were male. 53.3% belongs to middle class, 36.9% to lower class and 13.3%

to upper middle class. 33.3% of them were having higher secondary education. 26.7% were labour. In terms of *Prakriti* 46.7% were *Vata Kapha Prakriti* and 33.3% were *Pitta Kapha Prakriti*. 73.3% of them were have dandruff history. In chronicity, 66.7% were having a chronicity of approximately from three years and 13.3% from 1-2 years. (Table1).

TABLE: 1 DEMOGRAPHIC DATA

Variables		No. of patients	%
Gender	MALE	7	46.7 %
	FEMALE	8	53.3%
Education	Uneducated	1	6%
	Primary	4	27.7%
	Higher Secondary	5	33.3%
	Graduate	3	20%
	Post Graduate	2	13%
Occupation	Service	5	33.3%
	Labour	4	27.7%
	Business	0	0.0%
	Housewife	3	20%
	Student	3	20%
Socio-economic status	Lower Middle	5	33.3%
	Middle	8	53.3%
	Upper Middle	2	13%
Prakriti	VP	3	20%
	VK	7	46.7 %
	PK	5	33.3%
Dandruff History	No	4	27.7%
	Yes	11	73.3%
Chronicity	<1 YR	2	13%
	<2 YR	2	13%
	<3 YR	10	66.7%
	<4 YR	1	6%

Since the observations were on ordinal scale so, we used Wilcoxon Signed Rank Test to test the efficacy of therapy.

IN SUBJECTIVE CRITERIA

Arujam/ Alparujam/ Nishtoda (Severity of Pain)

Before treatment median score of Severity of pain in Right eye was 2.00 which reduced after treatment to 1.00 with a relief of 53.3% (p- value=0.000) which is statistically significant. Before treatment median score of Severity of pain in Left eye was 2.00 which reduced after treatment to 1.00 with a relief of 55.2% (p- value=0.000) which is statistically significant.

Kandu (Itching at Eyelids)

Before treatment median score of Itching at eyelids in Right eye was 2.00 which reduced after treatment to 1.00 with a relief of 51.5% (p- value=0.000) which is

statistically significant. Before treatment median score of Itching at eyelids in Left eye was 2.00 which reduced after treatment to 1.00 with a relief of 51.5% (p- value=0.000) which is statistically significant.

Burning Sensation

Before treatment median score of Burning sensation in Right eye was 1.00 which reduced after treatment to 0.00 with a relief of 71.4% (p- value=0.001) which is statistically significant. Before treatment median score of Burning sensation in Left eye was 1.00 which reduced after treatment to 0.00 with a relief of 71.4% (p- value=0.001) which is statistically significant. (TABLE 2).

TABLE: 2 Subjective Criteria

Parameters	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Arujam/alparujam/Nishtoda (Severity of Pain) RE	2	1	-3.557 ^a	0.000	53.3	Sig
Arujam/alparujam/Nishtoda (Severity of Pain) LE	2	1	-3.557 ^a	0.000	55.2	Sig
Kandu (Itching)RE	2	1	-3.690 ^a	0.000	51.5	Sig
Kandu (Itching)LE	2	1	-3.690 ^a	0.000	51.5	Sig
Burning Sensation RE	1	0	-3.217 ^a	0.001	71.4	Sig
Burning Sensation LE	1	0	-3.217 ^a	0.001	71.4	Sig

IN OBJECTIVE CRITERIA***Antahklinnata/ Srava (Discharge/ Matting of eyelashes)***

Before treatment median score of Matting of eyelashes in Right eye was 2.00 which reduced after treatment to 1.00 with a relief of 50.0% (p- value=0.001) which is statistically significant. Before treatment median score of Matting of eyelashes in Left eye was 2.00 which reduced after treatment to 1.00 with a relief of 54.3% (p- value=0.001) which is statistically significant.

Bahyatah Shunam (Lid oedema)

Before treatment median score of Lid oedema in Right eye was 2.00 which reduced after treatment to 1.00 with a relief of 48.5% (p- value=0.000) which is statistically significant. Before treatment median score of Lid oedema in Left eye was 2.00 which reduced after treatment to 1.00 with a relief of 45.5% (p- value=0.000) which is statistically significant.

Scaling at lids

Before treatment median score of Scaling at lids in Right eye was 2.00 which reduced after treatment to 0.00 with a relief of 80.6% (p- value=0.000) which is statistically significant. Before treatment median score of Scaling at lids in Left eye was 2.00 which reduced after treatment

to 0.00 with a relief of 77.4% (p- value=0.000) which is statistically significant.

Conjunctival Scaring

Before treatment median score of Conjunctival scaring in both eyes was 0.00 which reduced after treatment to 0.00 with no change 0.0% (p- value=1.000) which is statistically not significant. Median was 0.00 before treatment because in maximum (more than half i.e.12) number of patients had conjunctival scaring Grade 0.

Falling of Eye Lashes

Before treatment median score of Falling of eyelashes in Both eyes was 1.00 which remained after treatment to 1.00 with a relief of 37.5% (p- value=0.014) which is statistically significant.

MGE (Meibomian gland expression)

Before treatment median score of M.G.D in Right eye was 2.00 which reduced after treatment to 1.00 with a relief of 61.8% (p- value=0.000) which is statistically significant. Before treatment median score of M.G.D in Left eye was 2.00 which reduced after treatment to 1.00 with a relief of 64.7% (p- value=0.000) which is statistically significant. (TABLE 3).

TABLE-3 Objective Criteria

Parameters	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
<i>Antahklinnata/Srava (Matting of eyelashes) RE</i>	2	1	-3.419 ^a	0.001	50.0	Sig
<i>Antahklinnata/Srava (Matting of eyelashes) LE</i>	2	1	-3.416 ^a	0.001	54.3	Sig
<i>Bahyatah Shunam (Lid oedema) RE</i>	2	1	-3.771 ^a	0.000	48.5	Sig
<i>Bahyatah Shunam (Lid oedema) LE</i>	2	1	-3.873 ^a	0.000	45.5	Sig
<i>Scaling at lids RE</i>	2	0	-3.542 ^a	0.000	80.6	Sig
<i>Scaling at lids LE</i>	2	0	-3.487 ^a	0.000	77.4	Sig
<i>Conjunctival Scaring RE</i>	0	0	.000 ^b	1.000	0.0	NS
<i>Conjunctival Scaring LE</i>	0	0	.000 ^b	1.000	0.0	NS
<i>Falling of Eye Lashes RE</i>	1	1	-2.449 ^a	0.014	37.5	Sig
<i>Falling of Eye Lashes LE</i>	1	1	-2.449 ^a	0.014	37.5	Sig
<i>MGE (Meibomian gland expression) RE</i>	2	1	-3.520 ^a	0.000	61.8	Sig
<i>MGE (Meibomian gland expression) LE</i>	2	1	-3.508 ^a	0.000	64.7	Sig

DISCUSSION

Eyes are most beautiful creation of god and diseases of eyelids can disfigure the person. The patients always experiences physical, emotional & socio-economic embarrassment in the society. *Vidalaka* can improve the eyelids disorders. Deep penetrating properties of the drugs can easily penetrate across the skin of eyelid through the appendageal roots. The thickness and integrity of stratum corneum is an important factor determining the transdermal drug absorption. Thicker skin is a greater barrier to passage of the drug. The skin of eyelid is the thinnest in the body and it measures approximately 0.05cm. The basal layer of the epidermis of eyelid shows the presence of unicellular sebaceous glands and numerous typical eccrine sweat glands. The

dermis is composed of rich network of elastic fibres, blood vessels, lymphatics and nerves.^[8]

Percutaneous penetration of a drug occurs through the stratum corneum, underlying viable epidermis, dermis, and then finally into the circulatory and lymphatic system. Percutaneous penetration may occur through the intercellular, transcellular, and appendageal routes. Mechanical pressure exerted on the eyelid margin remove debris, bacteria, bacterial toxins, scales and crusts from the minute folds of the skin and thereby helps to maintain the lid hygiene. The drug also improve the vascular supply of the eyelid which in turn helps in faster and effective absorption.

Probable mode of action of Vidalaka Karma

After *Vidalaka* application there is release of active principles they enter at proper site in skin^[9] then absorption takes place after that *Pachana* by *Bhrajakagni*.^[10] occurs then new metabolites formation takes place then pacification of *Doshas* occurs which leads breaking of pathogenesis and alleviation in the symptoms occurs. The active principles of the *Lepa* reach to the deeper tissues through *Siramukha* & *Swedavahi Srotas* & stains it with its *Sukshma* & *Tikshna* property. Due to *Ushna*, *Tikshna*, *Vishad* & *Sukshma* properties it deblocks the obstruction in *Swedavahi Srotas* & allows the local toxins to flow out through the *Sweda*, thus clearing out the micro channels.

Actions of Vidalaka Yoga

Tikta Rasa shows its *Chedana* property; *Katu Rasa* is *Tikṣṇa* and possesses *Mārga Vivarana* action. Due to *Sukṣma Guṇa* after assimilation, drug approaches at the minute level (cell) of the body. *Uṣṇa Virya* has *Lekhana*, *Chhedaniya*, *Sodhana*, *Rasāyana*, *Cakṣuṣya* and *Kaphanāsaka* effect. *Slesmopasosana* properties are possessed by *Tikta*, *Katu Rasa*. *Kāṣāya Rasa* shows its *Kleda Soṣaṇa* and *Sleṣma Prasamana* properties.

TABLE- 4 (Overall effect of therapy)

Overall Effect	Frequency	%
Cured	0	0.0
Marked Improvement	5	33.3
Moderate Improvement	8	53.3
Mild Improvement	2	13.3
No Improvement	0	0.0

CONCLUSION

Vidalaka Karma in eyelid disorders has shown a promising results in the reduction of signs and symptoms of *Praklinna Vartma*. However clinical trials on a large sample with long duration of follow up is necessary to establish the efficacy of *Vidaalak Karma* as a procedure of choice and to analyse the recurrence rate after treatment. Thus it can be concluded that *Vidalaka Karma* can be advised for successful treatment in patients of *Praklinna Vartma*.

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Because of the above said inherent properties of the drugs, after getting absorbed it may scrap away the vitiated *Kapha* lodged in the Lids. The *Suddha Srotasa* (opened channel) allowed free movement of *Vāta Pitta* and *Kapha*. Ingredients of *Vidalaka Yoga* are having *Karmas* (actions) like *Tridosahara*, *Chakshusya*, *Krimighna*, *Kandughna*,^[11] *Twakadoshahara* and *Raktashodhaka*.^[12]

OVER ALL EFFECT OF THERAPY

- The present study shows that 05 patients (33.3%) showed marked improvement, 08 patients (53.3%) showed moderate improvement, 02 patients (13.3%) showed mild improvement and no patient (0.0%) showed no response or cured by treatment.
- None of the patients remained unchanged/uncured in treatment group.
- In none case, any sign and symptom of the recurrence & incontinence was ever found out during study period or follow up.
- No adverse reaction of any drugs/procedure was observed during the course of study and post treatment follow up. (TABLE 4).

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