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# A POTENTIAL EFFICACY OF POLYHERBAL FORMULATION IN THE MANAGEMENT OF BLEPHARITIS (KRIMIGRANTHI)-

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#### **ABSTRACT**

One of the irritating and inflammatory condition of eye lid margin occurs in all age group irrespective of sex, being a extraoccular disease it not only affects the anatomy of the lid but if left untreated can also leads to intraocular complications too as the treatment is concerned there is no satisfactory treatment available in other medical science but Ayurved Science seems to be promising when treatment of blepharitis is concerned.

KEYWORDS: Krimigranthi, Blepharitis, Meibomian gland.

# **INTRODUCTION**

Eye lid base inflammation is one of the most common ocular surface disorder encounter by eye care professionals, it is called Blepharitis. Usually it occurs bilaterally but unilateral condition also appears. However this condition is due to its multifactorial etiology and presents with variable signs and symptoms. Occasionally it presents with other ocular surface disorders. Most of the time it appears in two forms divided in anterior Blepharitis and posterior, Blepharitis involving an infection and inflammatory condition of the external lamella of the eyelid and eye lashes, later involving inner lamella of the eyelid and meibomian glands. Posterior Blepharitis (Meibomian gland disorder –MGD) seems to be chronic condition and manifests in middle age but is also observed in childhood.<sup>[1,2]</sup>

Blepharitis is a chronic condition and can be associated with a variety of systemic diseases. e.g, Dermatitis, Dry eye syndrome, Conjunctivitis, or Corneal inflammatory disorders, Unhygienic lid usually propagate the disease often observed in poor people with low immunity. Clinical manifestation includes white scale along the eyelashes, eyelid margin may

be hyperemic, crusting, falling of eyelashes, Blockage of meibomian gland orifices, and tear film disorders. Blepharitis can be a familial inflammatory disorder of the eyelid recognized in 19<sup>th</sup> centuries. It has no permanent cure yet but can be controlled for few weeks to months currently there is no US FDA approved management on blepharitis.<sup>[3]</sup> The non-pharmacological approach is, hot fomentation and lid hygiene, provides some response to warm compress, lid scrub together collectively reduced lid margin debris, liquefy stagnant, partially solidified M.G., secretions and decrease bacterial counts, eyelid hygiene performed once daily is generally effective. Omega-3 dietary supplement improves tear production and stability.<sup>[4]</sup> Other remedies may enhance patients quality of life, relieve discomfort associated with contact lens wear improve ocular surgery outcomes, and prevent permanent ocular damage.

As the prevalence of blepharitis increases with age, eye care professional can expect to see a growing number of cases in future. In another published paper it may be present in 37% to 47% of all patient seen by eye professionals and optometrist. [5] It is estimated approximately 50% with increasing age and contact lens use, another study reported 39% of normal healthy person may be affected with this disorder. [6] To treat a blepharitis is very annoying and difficult condition. If left untreated may lead to corneal complications such as toxic epithelial keratitis, catarrhal ulceration or phlyctenulosis.

Blepharitis can be correlated with *krimigranthi* which is described in Ayurveda. In the disease of the eyelid disorders with similarity of symptoms explained in modern Ophthalmology. Ayurveda described its management with various measures, like *Aschyotana, Putpaka, Bidalaka*, etc. However according to Vagbhsta and Charaka, in early stage of eye disorders both have emphasize on *Bidalaka*<sup>[8,9]</sup>, on the other hand still there is no proper established guidelines regarding therapeutic measure of Blepharitis, but clinical trial have shown that application of *Bidalaka* can produce significant improvement in the signs and symptoms of Blepharitis.

This poly herbal formulation (PHF) is more effective and convenient treatment modality that addresses both infections and inflammation component.

In larger scale further trials are needed to determine optimal therapies to treat Blepharitis. Hence considering these entire factor, it was decided that to treat Blepharitis (*krimigranthi*) with effective polyherbal formulation along with very low cost effective management.

#### AIMS OBJECTIVES

The present study was planned to evaluate the clinical efficacy and safety of poly herbal formulation paste on involved ocular surface in Blepharitis.

#### Study design

This was an open non-comparative clinical study conducted during the period of 2010 to 2011, an informed written consent of all patients were taken along with local institutional ethics committee.

#### MATERIAL AND METHOD

Subjects were recruited at OPD and IPD, drug were identified and authenticate by the concern departments.

### Diagnostic criteria

Diagnosis was established on the basis of history and symptoms mentioned in the classical and modern text.

#### **Inclusion criteria**

Total 60 participants (112) eyes with clinical symptoms and signs of Blepharitis (Anterior Blepharitis) of either sex of all age groups, the patients who were presenting sign and symptoms of *Krimigranth*i with small white scale along the base of eyelashes, itching and swelling at the eyelid margin and falling of eye lashes, who were willing to give informed consent and institutional ethical committee clearance were enrolled in the study.

# **Exclusion criteria**

Those who are suffering from secondary to metabolic disorder, ulcerative Blepharitis, Trichiasis, Drooping eyelid, Psoriasis, Drug induced Blepharitis, Patients suffering from HIV, HbsAg, Malignancy, Bleeding disorders, patients who needs surgical and other intervention and not willing for trial are excluded from the study.

Essential Laboratory investigations were done, like CBC, ESR, HIV, HbsAg, Blood glucose level fasting and post meal, Lipid profile and Urine routine.

Preparation of poly herbal formulation was as per classic, viz, *Shigru, Vidang, Apaparga*, *Gokshur, Nirgundi*. In equal quantity of approximately 1gms each, in fine powder form and mixed with sterile water and prepared in paste form. The drug formation in Ayurvedic

classics is based on two principles, use as a single drug and use of more than one drugs, in which the latter is known as poly herbal formulation. Thus this key traditional therapeutic herbal strategy exploits the combination of several medicinal herbs to achieve extra therapeutic effect, usually know as polypharmacy or polyherbalism.<sup>[10]</sup>

#### **Duration of the treatment**

2 cycle of 10 days each with a gap of 7 days between each cycle, this paste applied over the eyelid except eyelashes, (As per Ayurvedic classics) kept the paste till it becomes dry completely, approximately 30 minutes, once in a day at morning.

#### Assessment criteria

The disease assessment and response of therapy was assessed base on following subjective and objective criteria.

#### Subjective assessment

1) Pakshma kandu (Itching at eyelashes margin).

Objective criteria- were White scale along eyelashes, falling of eye lashes and eyelid margin swelling.

#### Gradation done accordingly for objective criteria

*Pakshma kandu-*0, 1-mild (Tollerable itching),2-moderate (Intense form), 3-sevre (Intolerable), for subjective- i.e., 0 Absent, 1-Mild (sparsely visible), 2- moderate (More densely visible), 3-Severe(present densely over upper lid margin).

# **OBSERVATION AND RESULTS**

In the present study 60 subjects participated irrespective of sex and age. There were no. of patient in the age group of 71-80 year old (1.66%), patient in the age of 81-90 years.32 (53.33%) subjects belongs to male category and 28 (46.66) subjects were belong to *Vata*,17 (28.33%) and *pitta- kapha* 03 (5%), were noted. Incidence wise subjects were found *Pakshma kandu*, 60 (100%), White scale along the lashes 56 (93.33), eyelid base swelling 57 (95%), falling of eyelashes 53(88.33%), overall effect of therapy in all four symptoms amongst 60 participants, 81.25% relief was seen in *pakshma kanddu* (eye lid base itching), 78.41% relief was observed in white scale along the lashes,35.71% relief was seen in *pakshma –vartma sandhi shotha* (Union of lid margin and eyelashes) and 4.255 relief was seen in *pakshma – kshaat* (Fall of eyelashes).

As per Wilcoxon match paired sign rank test, sum of all signed rank was 1653, the number of pair were 57, Z – value was 6.56, which was extreme significant, p<0.0001 in *pakshma kandu*. In white scale along the lashes sum of all signed rank was 1431. The number of pair were 53, Z-value was 6.33, which was statistically significant, p<0.0001 and In *pakshma* – *vartma sandhi shotha* sum of all signed rank was 630, the number of pairs were 35, Z- value was 5.15, statistically significant, p<0.001, and in *pakshma- kshaat* sum of all signed rank was 10, the number of pairs were 05, Z- value was 1.82, which was statistically not significant, p<0.1250. Showing over all percentage of improvement/ relief in patient is excellent. Relief in02 patient 3.33%, good relief in 24 subjects was 40 %, moderate relief in 19 subjects was 31.66% and mild relief in subjects 15% and not significant relief was observed in 06 subjects.

# 1) BEFORE



# **AFTER**



2)





Sr. No.	Symptoms	Mean	S.D	S.E	W	N	Z	P
1	Pakshma kandu							<0.0001
	BT	2.400	0.6162	0.07955				
	AT	0.450	0.5945	0.07675				
	Diff	1.950	0.8719	0.1126	1653	57	6.56	
2	White scales along the							
	lashes							
	BT	2.317	0.8129	0.1049				< 0.0001
	AT	0.500	0.6244	0.08061				
	Diff	1.817	1.033	0.1334	1431	53	6.33	
3	Pakshma vartma sandhi							
	shotha							
	BT	1.867	0.6756	0.08199				< 0.0001
	AT	1.200	0.6587	0.08723				
	Diff	0.666	0.6289	0.08504	630	35	5.15	
4	Pakshma shaata	1 5 6 7	0.0511	0.1000				
	BT	1.567	0.8511	0.1099				0.1050
	AT	1.500	0.8537	0.1102	10	0.4	1 02	0.1250
	Diff	0.666	0.2515	0.03247	10	04	1.82	

#### **DISCUSSION**

The effect of local application and delivery system of polyherbal paste potentially deliver the effective improvement in clinical signs and symptoms without local and systemic adverse effects. This local application of ophthalmic poly herbal preparation can be advantageous it delivered with high drug concentration directly to the extra- ocular surface. This drug may enhances its stability and bioavailability on the ocular surface because it's a natural poly herbal paste without giving any heat or pharmacological procedures except mixed with sterile water. The paste is remains on the ocular surface till it becomes complete dry. i.e., up to maximum 45 minutes, with this procedures the drug might produced sustained release of medicinal properties with prolonged local action and availability on the ocular surface which helps to enhances the penetration of the drug on the eyelid and its margins gives local lukewarm effect, moisture effect on the ocular surface thus increasing its potential as a treatment of Blepharitis.

The poly herbal preparation having *krimignha* properties, they mainly posses *katu-tikta*, *kashya rasa*, *katu vipaka*, and *kledagnha* properties acts against *kapha* and *vata* predominant disorder, also acts against *shotha*, therefore most of the plants acts as *shothagnha* i.e. to reduced inflammation.

#### **CONCLUSION**

After searching different types of literature on Blepharitis classical management is still inadequate due to its chronicity. Hence for better treatment modalities poly herbal formulation is the overall acceptable solution even for local complications and also maintains the long term disease controlling capacity. This PHF may a novel therapy of Blepharitis with better efficacy and safety.

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