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# AN OPEN LABEL SINGLE ARM CLINICAL STUDY ON DARVADYANJANA IN THE MANAGEMENT OF PRASTARI ARMA (PTERYGIUM)

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#### **Background:**

### ABSTRACT

Prastari arma is one of the suklagata netrarogas explained in classical texts. Classical definition of arma is moreover similar to features of Pterygium in contemporary science. It is a common problem in Shalakya clinical practice. The prevalence of the disease mostly seen in global rural community and in central India is about 13% among adults >30 years of age. The older age, male gender, lower literacy and exposure to pollution and high temperature, sunlight are the chief causes. Due to asymptomatic nature of the disease, ignorance of the patient and non-availability of medical treatment are the main hurdles in management. Recurrence rate is also high after surgery. A wide variety of treatment principles like Lekhana and Chedana karma are explained in the classics for Prastari arma. Here, Darvadyanjana had been selected for the study.

#### **Objectives:**

To evaluate the efficacy of Darvadyanjana in the management of Prastari arma (Pterygium) Materials and Methods:

Study Design: An open label single arm clinical trial with pre hoc and post hoc test design.

Sample: 30 patients of Prastari arma (Pterygium) fulfilling all the inclusion criteria were selected from OPD and IPD Shalakya Tantra department of SDM College of Ayurveda and Hospital, Hassan, Karnataka by convenience sampling method.

Drug: Darvadyanjana 2 drops BD for 60 days was administered into affected eye.

**Results:** The Darvadyanjana was found to be statistically significant on the associated symptoms like vedana, ragata, garsa and srava as well as insignificant on mamsa vridhi.

#### **Conclusions:**

Darvadyanjana is significant for associated symptoms while insignificant on mamsa vridhi in Prastari arma. **KEYWORDS:** Prastari arma; Pterygium; Lekhana anjana; Darvadyanjana.

# **INTRODUCTION**

Ayurveda is a natural system of medicine that has been practicing for thousands of year in India. Eyes are one of the most sensitive and vulnerable organs in the body by which one can see the beauty of world.1 Sushruta mentioned 76 types of eye diseases among which 11are Shuklagata Rogas.<sup>2</sup> Arma is a disease affecting the Netra shuklabhaga, characterized by a fleshy growth which is progressing towards the krisnamandala. There are mainly five types of Arma which can be correlated with Pterygium in contemporary science. Pterygium is a wing like triangular growth of the conjunctiva that encroaches towards the cornea from either side within the interpalpebral fissure.<sup>4</sup> The causative factors of Arma include exposure to dust, sun light, smoke, variation in seasons, unhygienic conditions and Asatmya ahara vihara.<sup>5</sup> The disease is common in both developed and developing countries. The prevalence of the disease is in all age groups and both genders. It can result in the symptoms like foreign body sensation, discomfort, defective vision and cosmetic disfigures of the eye. It is a major public health issues in the rural areas of developing countries. Present clinical research work was planned to find out a remedy for Prastari arma.

# NEED FOR THE STUDY

Prastari arma is one of the very common suklagata netrarogas in Shalakya practice. The prevalence of the disease mostly seen in global rural community and in central India is about 13% among adults >30 years of age. Due to asymptomatic nature of the disease and non-availability of medical treatment are the main hurdles in management. Recurrence rate is high after surgery.

A wide variety of treatment principles are explained in the classics for Prastari arma such as Lekhana, Chedana and Anjana. Among them "Anjana" is user friendly thus selected for study. For this study Darvadyanjana<sup>6</sup> was selected which consists of Daruharidra and Honey having chakshushya, chedana, Lekhana and kapha-pitta samaka properties which helps in removal of vitiated Kaphadi Doshas and Dushta Mamsa.<sup>7</sup>

# MATERIALS AND METHODS

1. Study Period: 2 months.

2. Inclusions Criteria:

- Membranous growth in conjunctiva of eyes
- Discomfort in the eyes
- Watering of eyes
- Foreign body sensation in eyes
- Redness in conjunctiva of eyes
- Patient with 20 to 70 years of age
- Willing and able to participate and ready to sign consent form

# 3. Exclusions Criteria:

- Pseudopterygium
- Patients having any inflammatory diseases of the eye
- Patient hypersensitive to the Darvadyanjana

# 4. Diagnostic Criteria

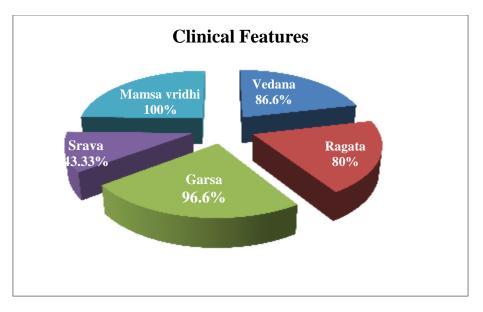
- I. Subjective Criteria:
  - Mamsa vridhi (Membranous growth in conjunctiva of eyes)
  - Vedana (Discomfort in the eyes)
  - Srava (Watering of eyes)
  - Garsa (Foreign body sensation in eyes)
  - Ragata (Redness in conjunctiva of eyes)

### II. Objectives Criteria:

• Pictorial presentations of the arma before and after treatment

### **OBSERVATIONS & RESULTS**

Study showed the majority of the patient were female (63.3%) and belonged to 30 to 40 years of age group of low socioeconomic status. Out of 30 patients, mamsa vridhi was seen in all 30 patients, Vedana was seen 26 patients, srava was seen in 13 patients, Garsa was seen in 29 patients and Ragata was seen in 24 patients.



# RESULTS

The entire result of the parameters taken for diagnostic criteria in the study had been compiled in the following tables. These data showed, the effect of the drug over associated symptoms of Prastari arma was statistically significant while for mamsa vridhi it was insignificant.

Friedman's test										
Symptoms	Mean	Rank	Ν	X <sup>2</sup>	Df	Р	*Remarks			
	BT	AT								
Vedana	5.85	2.85	26	104.667	5	0.0001	S			
Ragata	5.79	2.75	24	89.834	5	0.0001	S			
Garsa	5.33	2.33	29	107.807	5	0.0001	S			
Srava	5.85	2.85	13	53.312	5	0.0001	S			
Mamsa	3.42	3.52	30	5.000	5	0.416	N			
Vridhi										

\*S= significant, N= not significant

# Wilcoxon Signed Rank Test (Bonferroni correction = 0.00833)

Parameters BT-AT	Negative ranks		Positive ranks			Ties	Total	Z-value	P- value	*Remarks	
	N	MR	SR	N	MR	SR					
Vedana	26	13.50	351	0	0.00	0.00	0	26	-5.099	0.0001	S
Ragata	24	12.50	300	0	0.00	0.00	0	24	-4.811	0.0001	S
Garsa	29	15.0	435	0	0.00	0.00	0	29	-5.385	0.0001	S
Srava	13	7.00	91	0	0.00	0.00	0	13	-3.606	0.0001	S
Mamsa Vridhi		Friedman's Test showed the obtained 'p' value (= 0.416) was more at the level significance 'p' value <0.05 i.e. insignificant. Hence, Wilcoxon Signed Rank Test will be also insignificant.									

\*S= significant

#### PICTORIAL PRESENTATION

Out of 30 patients, Vedana (pricking pain), Ragata (Redness), Garsa (Foreign body sensation) and Srava (Watering of eye) was found to be significant

reduction during BT and AT except on Mamsa vridhi (Pterygium) as seen by photographic images.



# DISCUSSION

#### **Discussion on Drug**

Nidanas explained in Ayurvedic classics are acting as initiating and precipitating factors for Prastari arma. Darvadyanjana consists of Daruharidra having Antimicrobial, Anti inflammatory, Analgesic, Antipyretic, Cytotoxic and Anti-oxidant properties<sup>8</sup> and Madhu having Anti inflammatory, Antimicrobial, Antioxidant and wound healing properties.<sup>9</sup>

#### **Discussion on Demographic Data**

Among the demographic data, the age group 30-40 years and lower middle socioeconomic classes (53.3%) were highly prone to develop Pterygium because of working age group and poverty respectively.

### **Discussion on aggravating factors**

This study showed the major aggravating factors 63.3% were exposure to sun. Ultra violet radiation present in the sun light is one of the major factors to cause elastotic degeneration in the conjunctival epithelium and leads to development of Pterygium.<sup>12</sup>

#### **Discussion on Therapy**

The properties of Daruharidra and Honey acts synergistically over the symptoms of Prastari arma viz. Vedana, Ragata, Garsha and Srava and found statistically significant. And even after follow up, there was no recurrence of the symptoms. For mamsa vridhi, subjective study showed positive response in relieving the symptoms but pictorial presentation showed no change. This was due to short duration of intervention, the action of drug over mamsa vridhi might not have observed in significant reduction. Hence, longer duration of therapy may be needed to assess the result over mamsa vridhi in Prastari arma.



#### CONCLUSION

- Darvadyanjana was effective in reducing the symptoms of Prastari arma like vedana, srava, garsha, and ragata.
- The action of Darvadyanjana on mamsa vridhi (membranous growth) was found to be statistically insignificant due to smaller duration of therapy. Hence, null hypothesis was accepted.
- Satisfactory results were obtained in sustainability of the remission of the symptoms.
- The study showed there was no systemic as well as local adverse effect.
- Rasayana property of all these drugs helped in arresting the further degeneration of the tissue.

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