

**RANDOMIZED CLINICAL TRIAL TO STUDY EFFECT OF  
PIPPALYADI ANJANA ON PRASTARI ARMA WITH SPECIAL  
REFERENCE TO PROGRESSIVE PTERYGIUM**

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**ABSTRACT**

Eye is one of the important sense organ in human body. Even though our eyes are one of the most precious organs in our body, people tend to neglect to care them and pay very less attention until there is serious vision affecting problem. Pterygium is one such eye disorder found commonly. Pterygium is elastic degeneration of deep conjunctiva layers resulting in fibro vascular tissue proliferation. Pterygium mentioned in modern science shares clinical profile with *Arma* based on its clinical presentation, location, surgical method of management; hence it is correlated directly to pterygium for the study purpose. *Kriyakalpas* are the main mode of management in all types of *Nethra rogas* and *Anjana* is one of the simple yet very effective method of treatment in *Arma*. Here a randomized clinical trial is conducted to study the effect of *Pippalyadi Anjana* on *Prastari Arma* with special

reference to progressive pterygium. The results showed satisfactory effects.

**KEYWORDS:** Pterygium, *Prastari Arma*, *Kriyakalpas*.

**INTRODUCTION**

शालायनामोवजुगतानाोगानांवणनयाणादसंतानांयाधनामुपशम नाथ॥ (सु.सू.१/१०)

The eye is one of the most important and beautiful *Indriya* in human body. They are reflectors of mind. It is unique organ in the body where the course as well as pathophysiology of disease process is visible, agents can very well be assessed and if needed documented.

Even though our eyes are one of the most precious organs in our body, people tend to neglect to care them and pay very less attention until there is serious vision affecting problem. Ayurveda in its classical texts described *Arma* as *Shuklagata roga*, which describes this disease as *mansavridhhi* originating from *Kanika sandhi* or *Apang sandhi* or both sides towards *Drishtimandala* causing diminution of vision.

Pterygium mentioned in modern science shares clinical profile with *Arma* based on its clinical presentation, location, surgical method of management; hence it is correlated directly to pterygium for the study purpose. Pterygium which is common ocular surface disorder characterized by triangular fold of conjunctiva encroaching upon the cornea from either side within the interpalpebral fissure. The etiopathogenesis of pterygium is not fully understood. Environmental factors, such as ultraviolet light, chronic irritation have been implicated in various studies. Prevalence was higher in factory workers than in office workers, higher in rural areas than in the city and highest in fishermen. Geographic location and climatic conditions makes people here are highly prone to pterygium hence it is common ocular surface disorder in India especially in areas with higher temperatures. Pterygium mostly occurs in inter palpebral region in midline or slightly above or below the mid pupillary level. Pterygium is common in tropical countries like India. Pterygium is elastic degeneration of deep conjunctival layers resulting in fibro vascular tissue proliferation. Related to sunlight exposure and chronic irritation. Pterygium is treated primarily surgically though early cases can be treated conservatively with topical medicines. It affects patient symptomatically as well as cosmetically. Patients prefer surgical treatment as permanent cure. But even surgical treatment is associated with recurrence in few cases and more in increasing with post-operative bright sunlight exposure and dry eye patients. Also few old patients have co morbidity conditions as well as non-willing for surgery. Conservative medical treatment is not as much effective in most patients. Hence, these difficulties of modern science have stressed upon the need for the study for effective measure which can cure or control the condition and prevent recurrence. Hence keeping these lacunae in treatment for *Arma* in mind this study has been taken up to. *Kriyakalpas* are the main mode of management in all types of *Nethra rogas* and *Anjana* is one of the simple yet very effective method of treatment in *Arma*. Keeping its importance in *Nethra roga* prevention, *Acharyas* have advised for regular use of *Anjanas*, which protects the eyes from diseases affecting especially from *kapha*. For the medical management of *Arma Anjanas* especially *Lekhnjanas* are extensively quoted by our *Acharyas*. *Pippalyadi Anjana* is also one of the *lekhanajana yoga*.

Pterygium is a degenerative condition. The subconjunctival tissue undergoes elastic degeneration and proliferates as vascularized granulation tissue, which causes the further progression of the disease; hence use of antioxidant has received much attention as a part of medical management. The *Rasayana* approach provides drugs having antioxidant activity, regenerative, adaptogenic effects etc. which may be judiciously used to tackle degenerative problems of the eye. This study aims at prevention of growth of pterygium with medicinal treatment. The objective of the study is to evaluate the Efficacy of *Pippalyadi Anjana* in the management of *Prastari arma* also known as progressive pterygium.

## AIM AND OBJECTIVE

### Aim

“Evaluation of efficacy of *Pippalyadi anjana* on progress of *Prastari arma* with special reference to progressive pterygium”

## OBJECTIVES

1. Evaluation of efficacy of *Pippalyadi anjana* in the management of *prastari arma* with special reference to pterygium”
2. To evaluate the efficacy of *pippalyadi anjana* according to grades of pterygium
3. To compare the efficacy of *pippalyadi anjana* with carboxymethylcellulose 0.5% treatment

### Arma

Description of *Arma* is available in detail in all *Samhitas*. The detailed description is available in *Sushruta samhita Uttaratantra* 4th chapter *Suklagataroga Vijnaneeya Adhyaya*. *Astanga Sangraha* has explanation of *Arma* in 13th and 14th chapters of *Uttarasthana* and in *Astanga Hridaya* at 10th and 11th chapters of *uttarasthana*. References of *Arma* as quoted by *Acharya Nimi* and *Videha* are compiled by *Dalhana* in his commentary *Nibandhasangraha* on *Sushruta samhita uttaratantra* 4th chapter. *Arma* is also explained in *Bhavaprakasha Madhyama Khanda* 63rd Chapter, in *Netraroga chikitsaadhikara* of *Yogaratanakara*, *Chikitsasara sangraha* of *Vanagasena* in 71 chapter and in *Gadanigraha* 3rd Chapter. *Madhavakara* has explained about *Arma* at 59th chapter of *Madyama Kandha* and *Chakrapanidatta* has explained the *chikitsa* of *Arma* in *Netraroga Chikitsadhyaya*. References about *netra roga* and its *chikitsa* in detail are available in *Sahasrayoga* and *Chikitsa manjari*. *Sushruta* explains 11 different types of diseases which are occurring in *shuklamandala* of eye. The *Prastari arma*, *Shuklarma*, *Kshtajarma*, *Adhimamsarma*, *Snayuarma*, and *Shuktika*, *Arjuna*, *Pistaka*, *Sirajala*, *Sirapidaka* and *Balasagrathitha*.

*Acharya Vagbhata* adds *Sirotpata* and *Siraharsha* to the *shuklamandala vikaras*. Thus he describes thirteen *rogas* in *shuklamandala*.

#### *Nidana*

Sudden plunging into water after exposure to heat, excessive staring at distant objects, abnormal sleeping habits, continuous weeping, anger/grief/suffering, injury to head, excessive sexual intercourse, excessive use of vinegar and sour gruels, *kulatta* and *masha*, pulses, suppression of physiological calls of nature, excessive perspiration, smoking, suppression of excessive vomiting, suppression of tears, concentrating on minute objects. (S.Ut. 1/ 26-27).

#### *Purva rupa*

Dirtiness, congestion, lacrimation, itching, stickiness, heaviness, burning sensation, pricking pain, redness etc. are the prodromal features of the eye diseases. There may be feeling as if the cavity of the eye lids is full of painful bristles, impairment in vision or function of the eyes as compared with what they were before. As soon as the above features are seen, the intelligent clinician should regard that (eye) to have become afflicted with *Dosha*. (S.ut. 1/24)

#### *Samprapti* – pathogenesis

The *vimargagamana* of the increased *Dosha* through *Urdhwagaami siras* results in various complicated diseases of *netra*. When they get localized in *Shuklamandala* due to its susceptibility because of weakness caused by one or more *nidana* results in any of 11 *Shuklamandalagata rogas*.

##### *1 Prastari arma*

##### *2. Shukla arma*

##### *3. Kshtajarma*

##### *4. Adhimamsa arma*

##### *5. Snayu arma*

##### *6. Shuktika*

##### *7. Arjuna*

##### *8. Pistaka*

##### *9. Sirajala*

##### *10. Sirapidaka*

##### *11. Balasagrathitha*

*Roopa*

*Prastari arma* (pterygium) arising in the white portion is extensive, thin, having bloody luster & bluish. This is caused by *Tridosha* & is curable. (S.S.Ut.4 /4 p.601)

*Sukla arma* appearing in white portion is soft, whitish & even & has delayed growth. It is caused by *kapha* & is curable. (S.S.Ut.4 /4 p.601)

The fleshy tissue having lotus-like luster & growing in the white portion is known as *raktarma*. This is caused by *rakta* & is curable. (S.S.Ut.4 /5 p.601)

*Adhimamsa* is extensive, soft, thick, liver-like or blackish. This is caused by *sannipata* & is curable. (S.S.Ut.4 /5 p.601)

Fleshy tissue rough & pale, growing in white portion is known as *Snayu arma*. (SS.Ut.4/6 p.601)

**METHODOLOGY**

Source of data Patients were selected from the outpatient and inpatient departments of our parent institute.

**Inclusion criteria**

Patients above the age of 21 years and below the age of 60 years will be included, irrespective of their sex, on the basis of clinical signs and symptoms. The study included patients with Progressive Pterygium and those are not willing for Surgery. All patients having progressive pterygium will be included in study.

1. Age Group – 21 to 60 years of age.
2. Patients of both sexes will be selected.
3. Any eye right or left will be selected.
4. Patients willing to participate in the clinical trial & sign the informed written consent.
5. Patient with Progressive Pterygium which is not encroaching the pupillary area.

**Exclusion criteria**

- a. Patient having dry eye syndrome
- b. Patient having collagen vascular disease
- c. Patient with co-existent conjunctival diseases like previous alkali burns, moorens ulcer which predispose to pseudopterygium.
- d. Patient having atrophic pterygium.
- e. Patients having uveitis, scleritis, glaucoma

### Study design

This is a randomized case control study in which group A was treated with *pippalyadi anjana* application once a day and group B was treated with carboxymethylcellulose 0.5% was applied twice times a day. The duration of treatment was 45 days. Treatment period and follow up Duration of study – total 60 days duration Follow up – 5th, 14th, 21st, 28th, 35th, 45,60th day.

Group A - 40 Patients were subjected for *Pippalyadi anjana*.

Group B - 40 Patients were subjected for carboxymethylcellulose 0.5% eye drop

### Subject withdrawal criteria

Patients not comfortable with treatment Who decide to go for surgery Defaulters from study will be withdrawn from study Patients not willing to co-operate After seeing any adverse effect during study

### Preparation of the Drugs

#### Preparation of *Pippalayadya anjana*

*Pippali*, *Triphala*, *Laksha*, *Lodhra*, *Saindhava* are taken in equal quantity & pounded in *khalva yantra* till it becomes fine powder. *Vastraghalana* is done to get fine powder. This fine powder is taken, and then subjected to *bhavana* with sufficient quantity of *Bhringaraja swarasa* till it become soft in consistency preserved in air tight container.

### Duration and Mode of Administration of the Drugs

#### Group A *Pippalyadi Anjana*

The eye of the patient is opened with left hand. Then holding the *shalaka* dipped in *anjana* having *harenu matra* with right hand *anjana* is smeared from *kaneenika sandhi* to *apanga sandhi* on the inner side of the eyelid uniformly. It was applied once daily in the morning for 48days. When tears start flowing out of the eye, the eye is washed with lukewarm water or *triphala kashaya*.

#### Group B: carboxymethylcellulose 0.5% eye drop

The eye of the patient is opened with left hand. Then holding eye drop in right hand each eye was instilled with 2 drops of the drug. It was applied twice a day in the morning an evening for 48days.

Duration Of Treatment: 45 days

Follow up period: 60 days

Assessment criteria

Objective Parameters

Redness, Length, Thickness.

Subjective Parameters

***Vedana*, Foreign body sensation, *Daha*, Watering**

Grading	Redness
0	No redness (congestion of pterygium vessels) eye is quiet- i.e.white
1	Mild redness (congestion of pterygium vessels) eye is bright red with clear pattern of blood vessels is visible
2	Moderate redness (congestion of pterygium vessels) eye is red with poorly visible pattern of blood vessels
3	Severe redness (congestion of pterygium vessels) – eye is dark red with velvety conjunctiva or loss of blood vessel pattern

Grading	Length of pterygium
0	length > 1mm
1	length 1-2 mm
2	length 2-3mm
3	length more than 3 mm.

Grading	Thickness
0	Nil (no pterygium seen)
1	Clearly visible episcleral vessels under the body of Pterygium
2	Partially visible episcleral vessels under the body of Pterygium
3	Totally obscured episcleral vessels underlying the body of Pterygium

Grading	<i>Vedana</i>
0	No <i>Vedana</i>
1	Tolerable Incontinous
2	Tolerable Continuous
3	Intolerable

Grading	<i>Daha</i>
0	Absent
1	Present

Grading	Watering
0	No watering
1	1-4 times a day
2	5-10 times a day
3	More than 10 times a day

Grading	Foreign body sensation
0	No Foreign body sensation
1	Mild Foreign body sensation

2	Moderate Foreign body sensation
3	Severe Foreign body sensation

## OBSERVATIONS AND RESULTS

Forty Patients were selected in each of group (Group A and B). Group A was treated with *Pippalyadi Anjana*, Group B with carboxymethylcellulose 0.5 % eye drops. Subjective and objective changes were considered for the assessment of the efficiency of research work.

## RESULTS

### Group A

Parameter	Average		Difference (d)	% of diffe % d	SD	SE	P value	Remarks
	BT	AT						
Redness	2.225	1.475	0.75	33.70	0.493	0.080	<0.001	HS
Length	1.85	1.175	0.7	37.82	0.7232	0	<0.05	S
Thickness	1.9	0.6	1.3	68.42	0.22	0.061	>0.05	HS
Vedana	2.075	0.775	1.3	64.53	0.853	0.03	0.03	S
Daha	0.725	0.4	0.325	44.83	0.474	0.031	0.031	S
Watering	2.125	1.525	0.256	12.04	0.442	0.090	<0.001	HS
Foreign body sensation	1.95	1.725	0.225	11.53	0.423	0.063	<0.001	H S

### Group B

Param eter	Average		Difference (d)	% diff % d	SD	SE	P value	Remarks
	BT	AT						
Redness	1.975	1.175	0.85	43.03	0.495	0.802	<0.001	HS
Length	1.6	0.85	0.775	48.47	0.800	0.03	<0.001	HS
Thickens	2.025	0.775	1.25	61.72	0.269	0.031	<0.05	S
Vedana	2.075	0.975	1.1	50.50	0.841	0.082	<0.05	S
Daha	0.65	0.30	0.375	57.692	0.490	0.073	<0.001	HS
Watering	2.125	1.525	0.523	24.62	1.188	0.091	<0.001	HS
Foreign body sensation	2	1.725	0.275	13.75	0.452	0.077	<0.001	H S

### Inter Group Comparison of Effect Of

#### Treatments

Parameter	Group	Mea n	% differ	SD	SE	P-Value	Remarks
Redness	A	0.75	33.70	0.493	0.080	0.74	NS
	B	0.85	43.03	0.495	0.802		
Length	A	0.7	37.8	0.7232	0	0.392	NS
	B	0.775	48.47	0.800	0.03		
Thickness	A	1.3	68.42	0.22	0.061	0.0421	S

	B	1.25	61.72	3.7	0.269		
<b>Vedana</b>	A	1.3	64.53	0.853	0.03	0.294	NS
	B	1.1	50.50	0.841	0.082		
<b>Daha</b>	A	0.325	44.83	0.474	0.031	0.25	NS
	B	0.375	57.69	0.490	0.073		
<b>Watering</b>	A	0.256	12.04	0.442	0.090	0.034	S
	B	0.256	24.62	1.188	0.091		
<b>FBS</b>	A	0.225	11.538	0.423	0.063	0.0358	S
	B	0.275	13.75	0.452	0.077		

Showing the overall assessment of the results in the groups.

Response	Group-A	Group-B
	No of patients	No of patients
Good response	3	2
Moderate response	8	6
Mild response	25	27
Poor response	4	5

### Inference

*Pippalyadi Anjana* and Caboxymethylcellulose0.5 eye drop both are having significant improvement in clinical features of *prastari arma* (pterygium).

*Pippalyadi anjana* showed better response in thickness of pterygium.

Caboxymethylcellulose0.5 eye drop had better results watering and foreign body sensation.

While there was similar response in features of redness, length, *vedana* (pain) and *daha* (burning).

*Pippalyadi Anjana* primarily act against on the inflammation related to pterygium.

Caboxymethylcellulose0.5 eye drop focus on the maintaining lubrication of the ocular surface and promotes healing.

Their actions are complementary hence study involving combined required and may have great results.

Along with medication environmental changes and behavior changes like use of shaded eyeglasses increased blinking frequency, adequate sleep, reduced use of electronic gadgets also have additional effect.

Both drugs show good effect on treatment and may reduce need of surgery in significant number of patients also can have better effect in day to day life and positive impact on functional aspect of life.

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