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A CLINICAL STUDY TO EVALUATE THE EFFICACY OF *CHANDANADICHURNA ANJANA* ALONG WITH *SHATAVARYADI CHURNA* IN THE MANAGEMENT OF *SHUKLA ARMA* (NON- PROGRESSIVE PTERYGIUM)

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ABSTRACT

Shukla Arma (Non-progressive Pterygium) is one of the common ocular surface disorders described under *Shuklagata Netraroga* in Ayurveda. It is characterized by a slow-growing, white fibrovascular tissue extending from the conjunctiva towards the cornea. In modern ophthalmology, non-progressive pterygium is considered an atrophic fibrovascular degeneration of the conjunctiva, commonly associated with prolonged exposure to ultraviolet radiation, dust, wind, and dry climatic conditions. Although surgical excision remains the standard treatment, it is associated with a high recurrence rate and postoperative complications. Therefore, there is a need for a safe, effective, and non-surgical treatment modality. In Ayurveda, Shukla Arma can be managed by *Lekhana Anjana* when the lesion is small, thin, soft, and slowly progressive. *Chandanadichurna Anjana*, owing to its *Lekhana* and *Kaphahara* properties, along with *Shatavaryadi Churna*, which possesses *Kaphahara*, *Rasayana*, and *Chakshushya* properties, may provide an effective conservative management for Shukla Arma. **Methodology:** A prospective, open-label, single-arm clinical study will be conducted on 30 patients diagnosed with Shukla Arma (Non-progressive Pterygium) fulfilling the inclusion and exclusion criteria. All enrolled patients will receive *Chandanadichurna Anjana* (2 *Shalaka* once daily in the morning) along with *Shatavaryadi Churna* (6 g/day in divided doses with *Ghrita and Madhu*) for 30 days. Patients will be assessed before, during, and after treatment using subjective parameters including foreign body sensation, lacrimation, photophobia, and burning sensation, along with objective assessment of pterygium size using a Castroviejo caliper. Follow-up will be carried out on the 15th and 30th day.

KEYWORDS: *Shukla Arma, Non-progressive Pterygium, Chandanadichurna Anjana, Shatavaryadi Churna, Lekhana Anjana, Ayurveda, Shuklagata Netrarog*.

INTRODUCTION

Ayurveda is known as *Ashtanga Ayurveda* (A science with eight branches) & *Shalakya Tantra* is one of them.[1] *Shalakya Tantra* deals with the diseases of *Nayan* (Netra), *Shravan* (Ear), *Vadan* (Oral Cavity) and *Ghran (Nose).*[2]

Acharya Dhalana quoted that Eyes are important among the sense organ because the Day and night are same for a blind person, whole world is priceless. So, one should always do efforts for *chakshu Raksha.*[3] So any disorder which hampers the eye sight directly or indirectly should be in priority for the treatment.

Acharya Sushruta has mentioned 76 *netra roga* which further are divided into *Sandhigata* 09, *Vartamgata* 21, *Shuklagata* 11, *Krishnagata* 04, *Sarvagata* 17, *Drishtigata* 12, according to *Sthana* where they occur.[4] Among them *Arma* is considered under the 11 types of *Shuklagata netrarogas.*[5]

Arma (Pterygium) is a *Netrashuklagata Roga* characterized by *Mamsa Pratichaya* (growth of tissue) in

Shuklamandala, which progresses towards the *Krishnamandala* (cornea).

Arma is classified into 5 different types: *Prastari Arma, Shukla Arma, Lohita Arma, Adhimamsa Arma and Snayu Arma.*[6] According to modern science Pterygium divided as Regressive and Progressive Pterygium.[7]

According to *Ayurveda Shukla Arma* is characterized by *Mridu* (soft), *Shweta* (white), *Sama* (similar), *Vardhte Chirena* (slowly progressive)[8] while Non-Progressive Pterygium is characterized by atrophic, thin, attenuated with very little vascularity.[9] So on the basis of signs and symptoms *Shukla Arma* can be correlated with Non-Progressive Pterygium. Pterygium is a Greek word which means "wing". Pterygium is a triangular fibro-vascular growth of degenerated conjunctival tissue. Pterygium appears on nasal side, or rarely on temporal side of the cornea. Sometimes, both temporal and nasal sides are involved (double-headed pterygium).

Classically, a pterygium has four parts: (i) Head- a blunt apex, (ii) Cap- a few infiltrates in front of the apex (iii) Neck- a limbal part, and (iv) Body- a bulbar portion extending between the canthus and the limbus.[10]

AIM AND OBJECTIVES

Aim

To evaluate the efficacy of *Chandanadichurna Anjana along* with *Shatavaryadi Churna* in the management of *Shukla Arma (*Non-progressive pterygium).

Objective

- To study the *Arma* from various ayurvedic texts.
- Study of the Pterygium from modern texts.
- To assess the role of *Chandanadichurna Anjana* along with *Shatavaryadi Churna* in *Shukla Arma (*Pterygium).
- Correlation of *Shukla Arma* with Non-progressive Pterygium.

Research Question

Is there any effect of *Chandanadichurna Anjana* along with *Shatavaryadi Churna* in the management of *Shukla Arma* (Non-progressive pterygium)?

Hypothesis

Null Hypothesis (H_0)
Chandanadichurna Anjana along with *Shatavaryadi Churna* are not effective in the management of *Shukla Arma* (Non- progressive pterygium).
Research Hypothesis (H_1)
Chandanadichurna Anjana along with *Shatavaryadi Churna* are effective in the management of *Shukla Arma* (Non-progressive pterygium)

MATERIAL AND METHODS

To fulfil the aim and objectives, the study plan is divided into two sections.
Literary Review
Clinical Study

Study Design

Type of trial- interventional
Study Design- Open-label, single arm clinical study
Health type- patient suffering from Shukla Arma / Non-progressive pterygium
Purpose-To evaluate the efficacy of *Chandanadichurna Anjana* and *Shatavaryadi Churna in* the management of Shukla *Arma* (Non-progressive pterygium).
Timing- 30 days
Masking/Blinding- Open labelled
No. of groups- single arm study
Sample Size- 30
Phase of trial- 2
Estimated total duration of trial- 1.5yrs
Statistical tool: Appropriate tool will be applied

Selection of Patients: A total of 30 patients diagnosed with *Shukla Arma* (Non-progressive Pterygium) and fulfilling the inclusion and exclusion criteria will be selected from the OPD and IPD of the P.G. Department of Shalakya Tantra, Institute for Ayurved Studies & Research Hospital, Kurukshetra, after obtaining written informed consent.

Inclusion Criteria

- The person with age of >20 years and <60years.
- Patients with sign and symptoms of *Shukla Arma* (Non-progressive pterygium) will be selected irrespective of Sex, Religion and Profession.
- Clinical Features like White Fleshy Growth in S*uklamandalam* (white portion of eyes), foreign body sensation, and watering of eyes.
- Patients those are fit for *Anjana Karma* according to *Ayurveda* text.
- Patient willing to register for trial.

Exclusion Criteria

- Age: <20 years and >60 years
- *Anjana Ayogya*
- Progressive pterygium
- The patients in which Pterygium covers the pupillary margin.
- *Prastari Arma, Lohita Arma, Adhimamsa Arma, Snayu Arma*
- *Arma* (fleshy mass on the white portion of eyes) with any other ocular pathologies like *Abhisyanda, Adhimantha,* etc.
- Pseudopterygium
- Chemical injury: e.g., Lime burn or any other
- Chronic viral infections: e.g., Hepatitis C, HIV etc.
- Neurological conditions: e.g., Parkinson disease, Bell's palsy, Trigeminal neuralgia
- Immunological diseases – Autoimmune disease, collagen vascular and immunodeficiency.
- Pregnancy, Diabetes mellitus, Hyperlipidemia, Hypertension
- Patients not willing to be registered for trial.

Sources of Data

Literature Source: The literature related to *Shukla Arma* (Non-Progressive Pterygium) will be explored from Ayurvedic classics, modern literature, research journals & published articles.

Clinical Source: Daily OPD, IPD patients of Institute for Ayurved Studies and Research & patients diagnosed as *Shukla Arma* will be considered for the study after obtaining written informed consent.

Experimental Source: This was a human clinical study; no animal experimentation was conducted.

Interventions

1. *Chandanadichurna Anjana:* 2 *Shalaka* Once a day for 30 Days in Morning time

2. *Shatavaryadi Churna*: 6 gram in divided dose for 30 Days *Anupana*: *Ghrita* and *Madhu* (4 gm and 2 gm respectively)

Method of Preparation: The raw drug will be collected from authentic source and will be identified and approved by Department of *Dravyaguna* and formation of *Chandanadichurna Anjana and Shatavaryadi Churan* will be in pharmacy of *Rasa shastra* and *Bhaishjya Kalpana* of Institute for Ayurved Studies and Research, Kurukshetra.

Method Of *Anjana* Application

The whole procedure will be done in three steps after taking informed written consent, proper examination and investigations of patient.

***Anjana Karma procedure* divided into 3 parts**

1.*Purva karma*
2.*Pradhana karma*
3.*Pashchata karma*

1. *Poorva Karma*

Anjana should be applied in the early morning. To avoid the anxiety of the patient, the procedure should be explained to them. The patient is advised to lie in a supine position on a comfortable bed.

2. *Pradhana Karma*

The patient is asked to sit comfortably in a room devoid of sunlight, excess wind and dust. The physician should open the patient's right eye with his left thumb and index finger, holding the *Shalaka* in his right hand. The *Anjana* is applied over the lower fornix from medial canthus to lateral canthus and vice versa. The patient closes their eyes, rotates the eyeballs slowly, and is advised not to squeeze the eyes to help the *Anjana* spread fast. *Dosha Sravana* occurs in the form of watering.

3. *Pashchata karma*

The patient should close their eyes and move their eyeballs in all directions to ensure the collyrium spreads properly. The patient should not open or rub their eyes. After 5 to 10 minutes, the eyes should be washed with *kashaya* or lukewarm water. Following the irrigation, the eyelids should be gently pulled apart and inspected for any drug precipitates. If present, they are carefully removed with dry cotton wool to prevent discomfort.

Follow up: Follow up of patient will be done on 15th and 30th day of the treatment.

Assessment Criteria

Subjective Parameters

- Foreign body sensation
- Lacrimation
- Burning Sensation
- Photophobia

Objective Parameters

Measurement of *Arma* (Pterygium)

Length and width of whole pterygium will be measured before and after the treatment with the help of Castroviejo Calliper.

Outcomes

Primary

Reduction in sign and symptoms of *Shukla Arma* (Non-progressive pterygium).

Secondary

Improvement in quality of life of patient.

Sample Size

Sample size is calculated on the basis of expected cured % with trial drug using the formula:

$$n = \frac{\left(z_\alpha + z_\beta\right)^2}{\left[\ln\left(1-e\right)\right]^2}\left[\frac{1-p_1}{p_1} + \frac{1-p_2}{p_2}\right]$$

P_1 = 1.00 (100%) the proportion of pterygium before applying the trial drug

Where p_2 = 0.132 (13.2%) the proportion of pterygium after applying the trial drug (equal to the approx prevalence in general population)

(Ref : Nangia V, Jonas JB, Nair D, Saini N, Nangia P, Panda-Jonas S. Prevalence and associated factors for pterygium in rural agrarian central India. The central India eye and medical study. PLoS One. 2013 Dec 4;8(12):e82439.)

$e = 0.95(p_1 - p_2)$, the proportion difference considered to be clinically significant

Type I error, α=5%

Type II error β=10% for detecting results with power of study 90%

The sample size is n = 30

Ethical clearance & CTRI Registration

The study was registered with the Clinical Trials Registry of India (CTRI) with **CTRI NO. CTRI/2025/03/083155**

OBSERVATIONS AND RESULTS

The observation and results will be analyzed and presented in accordance with the respective and applicable statistical tests.

DISCUSSION

The obtained results will be discussed on the basis of Ayurvedic concept and modern parameters.

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