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*RESEARCH ARTICLE*

# "A PRE AND POST TEST STUDY TO EVALUATE THE EFFICACY OF VIBHEETAKYADI MASHI ANJANA IN THE MANAGEMENT OF SUKLARMA (PTERYGIUM)".

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## *Abstract*

**Background**: Suklarma is a soft uniform growth of Mamsa (fleshy growth) in white portion of eye that grows slowly to Krishna Mandala (Cornea). It can be compared with Pterygium in modern ophthalmology. The World wide prevalence of Pterygium is 10.2 %. The main method of treating Pterygium is surgical excision which is associated with high rate of recurrence. This study, which analyzes the effect of Vibheetakyadi Mashi Anjana in the management of Suklarma, will assist in developing a cost-effective, non-surgical option in the management of pterygium.

**Methods:** Ayurvedic Treatment Protocol included Snehapana, Virechana, Nasya and Tarpana and follow ups.

**Results:** Out of the 30 registered patients, 83.33 % of patients got marked improvement where as 16.66 % of patients got mild improvement in both subjective and objective parameters.

**Conclusion:** The study was an open labelled clinical study with total number of patients being 30. The drug formulation under study was Vibheetakyadi Mashi Anjana whose reference was found Ashtanga Hridaya, a classical (Indian) Āyurvēda textbook. The signs and symptoms, before and after treatment were recorded and graded. The grades were compared using the software SPSS ver. 20.The results thus obtained showed mild to moderate relief of all signs and symptoms with no relapse in follow up periods. This proves that Vibheetakyadi Mashi Anjana is effective in management of Suklarma (Pterygium).



## Introduction:-

Arma (pterygium) is characterized by Mamsa Pratichaya (growth of flesh) in Sukla Bhaga (white portion) of Netra (eyes), which progresses towards the Kṛiṣhnamandala (Cornea) if left untreated. There are five types of Arma: Prastaryarma, Suklarma, Lohitarma, Adhimamsarma, and Snayvarma[1]. Suklarma, which may be correlated with pterygium in modern ophthalmology, was taken for the study. Pterygium is a triangular fibro-vascular sub-epithelial growth of degenerative bulbar conjunctival tissue that encroaches upon the cornea[2]. The worldwide prevalence of pterygium is 10.2%. It is more prone in tropical climates and may present with symptoms such as foreign body

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sensation, watering of the eyes, and defective vision. Conservative management provides only temporary relief from foreign body sensation and watering. Further progression of the disease warrants surgical intervention. Excision of the pterygium is associated with a high rate of recurrence, often with more aggressive behavior than the original lesion. Newer modalities of surgical intervention have been developed to avoid recurrence of pterygium; however, most of these are too expensive for the common public. The recurrence rates associated with the bare sclera technique of excision is 30-80 % and 2-39% by the conjunctival technique. The recurrence rate for primary pterygium is 2.6-10.7% and 37.5 % for recurrent Pterygium by amniotic membrane grafting[3]. Suklarma may be treated with Ouṣhada (medicines), Lekhana (scraping) and Chedana (excision) procedures. These treatments are employed in different stages. Lekhana Anjana (scraping type of collyrium) is prescribed in the initial stages of Suklarma. Lekhana property is indicated in Suklarma as it is a Kapha-predominant Vikara (disease). The Lekhana Anjana is indicated when the Suklarma is Tanu (thin) and Dadhinibha (looking like curd), and also before the Arma encroaches cornea[4]. Vibheetakyadi Mashi Anjana, which is mentioned in the 11th chapter of Ashtanga Hridaya Uttara Sthana, contains Vibheetaki (Terminalia bellarica), Saindhava (rock salt) and Souvarchala Lavana (black salt)[5]. Each of the ingredients is having Lekhana Guna, more Laghutwa and Vata-Pitta hara property.

## Materials and Methods:-

### Patients

The study involved a total of 30 patients diagnosed with Suklarma and was carried out in the P.G. department of Shalakya Tantra, Amrita School of Ayurveda, Kerala.

### Inclusion criteria

Patients between the ages of 20 and 60, irrespective of their sex and based on clinical signs and symptoms such as: Suklarma not encroaching the cornea, white fleshy Growth in Suklamandalam , foreign body sensation and watering of eyes.

### Exclusion criteria

Suklarma that has encroached the cornea, Arma associated with any other ocular pathologies, and patients contraindicated for Collyrium Therapy.

### Study design and duration

It was an open-label clinical trial in which 33 patients were registered. 3 dropped outs were there due to their tight working schedule. A control group was not employed as the study was a preliminary attempt to know the efficacy of this formulation. The duration of treatment was one month. Deepana pachana (enhancement of digestive fire and digestion of Ama), Snehapana (oleation therapy), Abhyanga (body massage), Swedana (fomentation) and Virechanam (Purgation) was done as Poorvakarm (pre-procedures). The dosages for Poorvakarma was flexible based on Rogibala ( Stamina of patient) and Vaya (age) of the patient. Anjana karma was given for 14 days with Kshalana (eye wash) as Paschat karma (post procedure).

**Table No 1:-**Study design and duration

| | |
|---|---|
| Deepana-pachana | Vaiswanaram choornam for 2days |
| Snehapana | Moorchita goghrita (medicated cow's ghee) for 7 days |
| Swedana | Ushnodaka snanam (hot water bath) for 1 day |
| Virechana | Avipathi choornam for 1 day |
| Anjanakarma and Kshalana | Vibheetakyadi mashi for 14 days followed by eye wash with Luke warm water |

### Ethics

A written informed consent was obtained from each patient and the clinical protocol was approved by the institutional ethics committee.

### Trial drug

### Preparation of Vibheetakyadi mashi anjana

The Anjana was prepared with 250g each of Vibheetaki Mashi, Saindhava Lavana, and Souvarchala Lavana.

850 grm of dried Vibheetaki Twak was pounded and fine powder was prepared. This Choorna was made into a paste by adding Sudha jala (distilled water about 500 mi litr) to make Chakrika (flattened paste of fruit rind of Terminalia bellarica with water in coin size) and dried in sun . The Chakrikas (70 gm) were kept in Sarava (earthern vessel) and done Sandhi-bandhana (covered the vessel with another equal sized vessel and they joined together with cloths and mud). Puda (a kind of heating of earthern pots which are filled with medicines with the help of cowdung cakes) was done after proper drying of Sandhi Bandhana (joining). Vibheetaki Mashi (246 gm) was collected on next day morning. Bhavana (trituration) of Vibheetaki Mashi was done with 100 mL of Triphala Kvatha (decoction) to make paste form and put under sunlight for drying. After that it was collected , powdered and sieved using siever with Mesh no-120 Microns, BSS-120, M.M-0.125 mm. Finally the obtained powder was mixed with equal quantities of fine powders of Saindhava and Souvarchala Lavana.

**Dose and Time of administration**

Vibheetakyadi Mashi was taken in Two Shalaka Matra and prepared Rasakriya out of it by adding 90mg of honey because of the discomfort and burning sensation of eye felt by the patient in Choorna form (powder form). The duration of Anjana karma was 14 days and was done in the mornings.

**Assessment**

Assessment was based on subjective and objective parameters before and after treatment. The subjective parameters were Watering and Foreign body sensation. The objective parameters were the vertical and Horizontal measurement of Suklarma using Vernier calipers.

**Parameter grading Index[6]**

**Grading of Watering of Eyes:**

1. Absent
2. Occasional watering
3. Continuous watering
4. Very severe watering

**Grading of Foreign body sensation**

1. Absent
2. Occasional Foreign body sensation
3. Intermittent Foreign body sensation
4. Continuous Foreign body sensation

The Vernier calipers reading for Horizontal and Vertical measurement of Suklarma was taken (in mm) before and after the treatment and in each of the follow ups

**Gradation Index for Overall responses**

The overall response was assessed based on the data obtained before and after the treatment. The percentage of improvement was calculated and graded in the following ways:

1. No improvement: less than 25 % relief in signs and symptoms
2. Mild relief: 25 % relief in the signs and symptoms
3. Moderate relief: 50 % to 75 % relief in the signs and symptoms
4. Marked relief: > 75 % relief in the signs and symptoms
5. Complete relief: 100 %relief

## Statistical analysis:-

The obtained data from the Subjective criteria were subjected to the Wilcoxon signed rank test and the Objective criteria for Paired‘t’ test. ‘P’ value less than 0.05 considered as statistically significant.

## Results:-

Wilcoxon signed rank test showed reduction in watering and foreign body sensation between Before treatment, After treatment, Follow up 1, 2, 3 & 4 with a mean negative rank of 15.50. This was found to be statistically significant at all the stages ($P<0.01$(Bonferoni Correction)). After treatment a significant change was obtained with

P value <0.0001. Horizontal and Vertical measurements of Suklarma between Before treatment, After treatment, Follow up 1, 2, 3 & 4 was statistically analyzed using Paired t test. It was found that the mean gradation of vertical measurement before treatment was 0.6867 which decreased into 0.5300 after treatment, statistically significant at P<0.0001. The mean gradation of Horizontal measurement before treatment was 1.3300 which decreased into 1.1433, statistically significant at P<0.0001. The improvement of subjective and objective parameters were sustained in all four follow ups.

**Table No 2:-**Shows Statistical analysis of watering and foreign body sensation

| Parameter | Mean Rank (Negative Rank) | Z Value | Significance level |
|---|---|---|---|
| Watering AT:BT | 15.50 | -4.916 | 0.0001 |
| Watering FU1:BT | 15.50 | -4.916 | 0.0001 |
| Watering Fu2:BT | 15.50 | -4.916 | 0.0001 |
| Watering Fu3:BT | 15.50 | -4.916 | 0.0001 |
| Watering Fu4:BT | 15.50 | -4.916 | 0.0001 |
| Foreign body sensation AT:BT | 15.50 | -4.916 | 0.0001 |
| Foreign body sensation FU1:BT | 15.50 | -4.916 | 0.0001 |
| Foreign body sensation Fu2:BT | 15.50 | -4.916 | 0.0001 |
| Foreign body sensation Fu4:BT | 15.50 | -4.916 | 0.0001 |

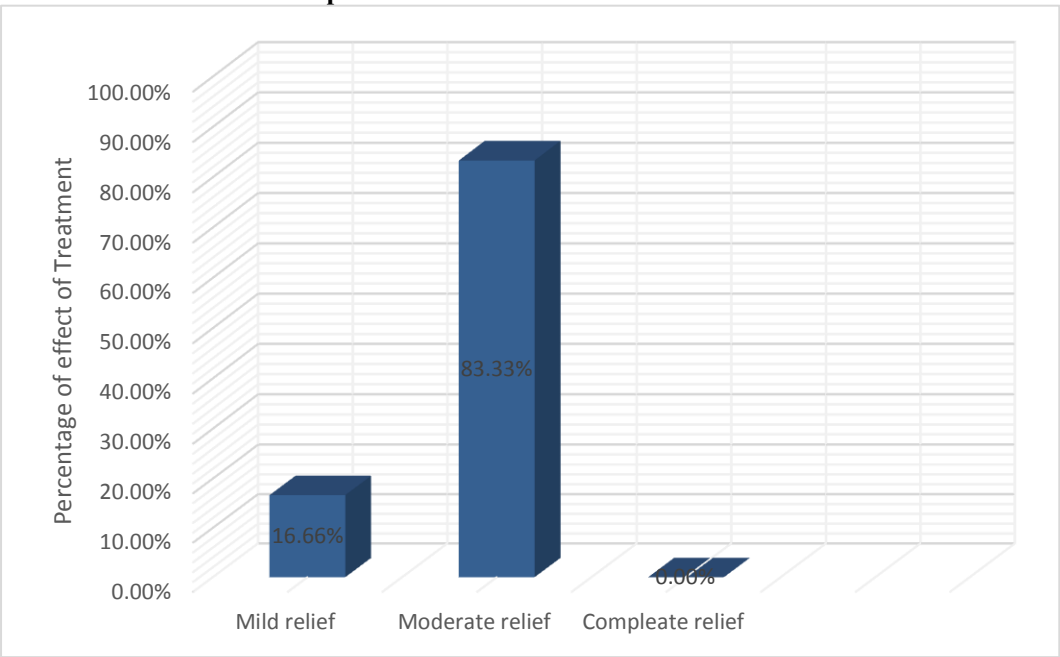
**Table No 3:-**Shows Statistical analysis of Vernier calipers Vertical and Horizontal measurement of Suklarma

| Parameter | % of improvement | SD | SE | Significant level |
|---|---|---|---|---|
| VC Vertical BT:AT | 22.81 | 0.07739 | 0.01413 | 0.0001 |
| VC Vertical BT:FU1 | 23.79 | 0.07184 | 0.01312 | 0.0001 |
| VC Vertical BT:FU2 | 23.79 | 0.07184 | 0.01312 | 0.0001 |
| VC Vertical BT:FU3 | 23.79 | 0.07184 | 0.01312 | 0.0001 |
| VC Vertical BT:FU4 | 23.79 | 0.07184 | 0.01312 | 0.0001 |
| VC Horizontal BT:AT | 14.03 | 0.06288 | 0.01148 | 0.0001 |
| VC Horizontal BT:FU1 | 14.03 | 0.06288 | 0.01148 | 0.0001 |
| VC Horizontal BT:FU2 | 14.28 | 0.06074 | 0.01109 | 0.0001 |
| VC Horizontal BT:FU3 | 14.28 | 0.06074 | 0.01109 | 0.0001 |
| VC Horizontal BT:FU4 | 14.28 | 0.06074 | 0.01109 | 0.0001 |

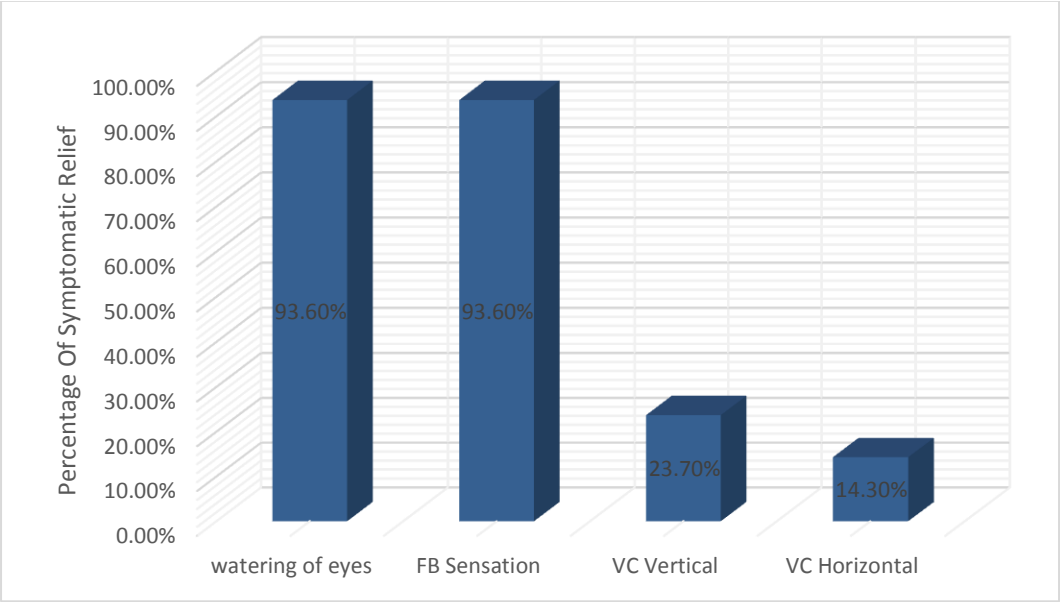
**Table No 4:-**shows Discussion on Observation

| Observation | Discussion |
|---|---|
| Age - 50 to 60 [63.3 %] | Prevalence increases with age |
| Gender – Men [56.7 %] | Men possibly are more exposed to UV rays |
| Principal occupation - Outdoor work [63.3 %] | Increased vulnerability to UV exposure, dust and smoke |
| Diet pattern - mixed [73.3 %] | Less intake of Vit A leads to Dry eye, which is a predisposing factor |
| Socioeconomic status Prevalent category – BPL [73.3 %] | Majority under agricultural and fishing activities. Chance of UV exposure is very high |
| Habitat – Rural [80 %] | Lack of awareness about eye protection measures |
| Chronicity - less than 2 years [70 %] | The rate of growth is high in People who engage out door activities |

**Graph no 1:-**shows overall effect of treatment




**Graph no 2:-**Shows overall symptomatic relief




## Discussion:-

Anjana is one among Netra kriyakalpas ( treatment procedures for eye diseases) having more tissue contact time and minimum disposal rate. Since Suklarma is a kapha predominant Vyadhi, Lekhanatva is needed for eliminating the Dosha from Suklamandala. Lekhana Anjana, by its Tikshna property eliminates the Doshas from Suklamandala, thus helping in reduction of the Arma mass. Mashi is nothing but an intermediate product of Bhasma, where both organic and inorganic types of constituents are present. By making Vibheetaki in to Mashi form, the particle size of Anjana reduces and attains more laghu guna, which helps in deep penetration of Anjana in Suklarma. Vibheetaki is having the Properties like kashaya rasa (astringent taste), Ushna veerya (hot potency), Kapha hartwa (reduce kapha) and Bhedana Guna (property of excision). It is also a Chakṣuṣya (good for eyes) dravya and also passifies Dosha dushti in Dhathus like Rasa, Raktha, Mamsa and Meda[7]. Souvarchala lavana is having Katu Rasa (pungent taste), Ushna Veerya (hot potency), and having Gunas (properties) like Laghu (light), Sukshma (subtle) & Visada (clear)[8,9,10]. Saindhava is Tridoshaghna (passifies all the Doshas)[11]. By analyzing the qualities of the individual drug

it may be inferred that all three ingredients of this Yoga (compound) is having Lekhana Guna and helps in Kapha Lekhana. Even though the compound drug Vibheetakyadi Mashi Anjana is a Lekhana Anjana, it has Tridoshahara property. Besides Souvarchala Lavana, the ingredients have the property of Pitta Haratva. The medium for rasakriya preparation was Madhu (honey), is having Gunas like Chedi (property of excision), Sleshma Haram, Kashaya-Madhura rasa and Chakshushya. Watering and foreign body sensation is due to Maamsa vridhi induced Vata–Pitta prakopa in Suklamandala. Mamsa Vridhi acts as a foreign body which hampers the uniformity of spreading tear film over the bulbar conjunctiva and results in dry eye. Dry eye is the cause for reflex hyperlacrimation and Foreign body sensation of eye. So reduction in Mamsa vridhi and Vata-Pitta hara property of the trial medicine help to reduce signs and symptoms of Suklarma

Gallic acid is the main Chemical constituent present in the fruit rind of Terminalia bellerica Roxb. It has Antimutagenic and antioxidant activity. The pathogenesis of Pterygium is associated with p53 oncogene expression, fibroblast transformation, and alterations in cytokines and matrix metalloproteinase activity. The antimutagenic activity of gallic acid prevents mutations of the p53[12]. The free radicals trigger degenerative process and progression of Pterygium. This can be prevented by Antioxidant activity of Gallic acid. Rock Salt and Black salts are other constituents of this Anjana. These have cleansing, Antioxidant and Anti-inflammatory activities. Honey has antioxidant activity.

## Conclusion:-

Statistically significant ie result ($P < 0.0001$) was obtained in subjective and Objective parameters of the present study. The disease is highly prevalent in older age group, male gender, Outdoor occupation, habituated in rural areas, and the people is under low socioeconomic status. Rural areas, including the coastal belt, were more exposed for the disease due to the intense ultraviolet radiation at sea level. The drug is quite safe and the ingredients were easily available. In this study the total days of Anjana karma is 14 days. In future, the numbers of days of Anjana karma can be extended for getting better results than the present study. The follow up period also can be extended for assessing the recurrence within years. The further opportunities in this area includes proper counseling among outdoor workers about the safety measures to be adopted like protective eyewear and goggles.

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