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An Open Label Double Arm Controlled Clinical Study of Shankhanjana in Arma(Pterygium)

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Abstract

Background: Pterygium is a common ocular surface disorder characterized by a triangular fibrovascular growth of conjunctival tissue extending onto the cornea, often associated with chronic exposure to ultraviolet radiation, dust, wind and environmental irritants. It presents with symptoms such as redness, irritation, foreign body sensation and may lead to visual disturbance in advanced stages. In Ayurveda, a comparable condition is described as Arma, classified under Shukla rogas and caused by vitiation of Tridoshas resulting in abnormal tissue growth. Despite surgical management being the mainstay in modern medicine, recurrence remains a concern, emphasizing the need for alternative and supportive therapeutic approaches.

Methodology: The present study was designed as an open-label randomized controlled clinical trial conducted on 40 patients diagnosed with Arma who satisfied the diagnostic and inclusion criteria. The participants were randomly allocated into two groups comprising 20 patients in each group. Group A (control group) was administered Guducyadi rasakriyanjana, while Group B (trial group) received Shankhanjana. The intervention was given for a duration of thirty days. Patients were assessed before treatment, immediately after completion of therapy and during follow-up (0, 30^{th}, 45^{th} day). The assessment was carried out based on subjective parameters such as Mamsavriddhi, Daha, Raga and Gharsha. The collected data were analyzed using appropriate statistical methods to evaluate the therapeutic efficacy of the intervention.

Results: The present study demonstrated that Shankhanjana produced a statistically significant reduction in the clinical symptoms of Arma ($p < 0.05$). Within-group analysis showed significant improvement after treatment. However, inter-group comparison did not reveal a statistically significant difference between the trial and control groups ($p > 0.05$). These findings indicate that the intervention is effective and comparable to the standard therapy.

Conclusion: Both the groups proved beneficial in reducing the symptoms of Arma and it may be considered as an effective and safe therapeutic option in the management of this condition.

1. INTRODUCTION

Eyes are one of the most delicate and important sense organs, playing a vital role in vision as well as in enhancing a person's appearance. However, because they are constantly exposed to dust, sunlight, wind and pollutants, they are highly prone to various disorders. One such common condition is pterygium, a triangular growth of tissue from the conjunctiva onto the cornea, which may cause redness, irritation and,

in advanced cases, affect vision. It is more commonly seen in people exposed to sunlight and outdoor environments, especially in tropical regions, with global prevalence reported between 2.8% and 33%. Pterygium is now understood as a condition influenced by multiple factors such as environmental exposure, chronic irritation and inflammatory changes in the eye. If not managed properly, it can gradually extend over the cornea and interfere with vision, apart from causing cosmetic concerns. Although surgical removal is commonly practiced, the chances of recurrence remain high, which creates a need for safer and more sustainable treatment options.

In Ayurveda, a similar condition is described as Arma, where abnormal tissue growth occurs over the white part of the eye due to imbalance of Kapha and Rakta doshas. Classical texts recommend both medical and surgical approaches depending on the stage, with simple procedures like Anjana being useful in early stages. Hence, exploring Ayurvedic management may offer a more effective approach for conditions like Arma (pterygium).

MATERIAL AND METHODS

METHOD OF COLLECTION OF DATA

STUDY DESIGN: Open label prospective double arm controlled Interventional clinical study with pre hoc and post hoc test design.

Sampling technique: Convenience Sampling.

Sample size: It was a comparative clinical study where in 40 subjects diagnosed as Arma (Pterygium) was randomly assigned into two groups i.e., Group A (Control Group) and Group B (Trial Group), each comprised of 20 patients.

SCREENING THE PATIENTS: Screening form which contained the Questionnaire to fulfill the inclusion and exclusion criteria and symptoms of Arma (Pterygium) was filled by principal investigator.

DIAGNOSTIC CRITERIA:

A. Subjective criteria

1. Daha
2. Gharsha

B. Objective criteria

1. Raga
2. Mamsavriddhi

ELIGIBILIGY CRITERIA: ICD-11-MMS CODE CA00–CB7Z

INCLUSION CRITERIA:

1. Patients aged between 30 to 60 years of either gender were selected.
2. Patients having the classical Lakshanas of Arma will be selected.
3. Encroaching of Pterygium limited to corneal margins.
4. Pterygium with both unilateral and bilateral will be considered.

EXCLUSION CRITERIA:

1. Patients with Autoimmune diseases that has caused Pterygium.
2. Pterygium with any other ocular pathologies.
3. Pseudopterygium and Pinguecula.
4. Patients with Chedhana yogya Arma as explained in classical text will be excluded

INTERVENTION:

Group A- Control group - Sample Size: 20	
Guduchyadi rasakriyanjana	Anjana done for 30 days
Duration of study	30 days
Assessment	• 0^{th} day diagnosis (before treatment) • • 30^{th} day assessment (after treatment) • • 45^{th} day Follow up

Group B- Trial group- Sample Size: 20	
Shankhanjana	Anjana done for 30 days
Duration of study	30 days
Assessment	• 0^{th} day diagnosis (before treatment) • • 30^{th} day assessment (after treatment) • • 45^{th} day Follow up

ASSESSMENT SCHEDULE

1^{st} assessment	Before treatment	DAY 0	Diagnosis, Screening
2^{nd} assessment	After Treatment	DAY 30	All the subjective & Objective parameters considered Assessment
3^{rd} assessment	After Follow-Up	DAY 45	All the subjective & Objective parameters considered Assessment

STATISTICAL METHODS:

ASSESSMENT CRITERIA- GRADATION INDEX

ASSESSMENT CRITERIA	**ASSESSMENT CRITERIA**
Mamsa Vriddhi on Shuklamandala	A. Width- widest part of Pterygium will be measured (Before treatment and After treatment)
	B. Length – from the canthus to the apex of the pterygium will be measured (Before treatment and After treatment) By- castroveijo caliper straight instrument
Daha	0 – Absent 1–occasionally present and open eyes easily 2 –frequently present but open eyes easily 3 –frequently present and open eyes with much discomfort
Raga	0 – Absent 1– Discrete, thin vessels vascular network limited to Pterygium 2– prominent vascular network limited to Pterygium 3–Congestion involving Bulbar conjunctiva and Circumcorneal zone.

Gharsha	0 – Absent 1 – occasionally present 2 – frequently present with lacrimation 3 – Continuously present with lacrimation and congestion

Withdrawal Criteria:
The participants were withdrawn from the study if there was any major ailment necessitating the institution of new modalities of treatment. The decision to withdraw a participant from the trial was taken by the PG Scholar with proper justification and formal information to the guide and the Ethics Committee within two working days.
Dropouts: 5 dropouts from each group were recorded during the clinical study.

Drug Compliance:
If there was more than or equal to 80% compliance, the participant was continued in the study. The compliance was assessed after treatment by structured interaction and Therapeutic drug monitoring where patient was instructed to carry the containers to assess the approximate quantity of Shankhanjana utilized during the study period.
Recording and Reporting of ADR:
No ADR was reported during the clinical study
Consent form:
Consent form was signed by each patient with their witness. An informed consent form was maintained for the study.
Confidentiality of data:
The personal data of the patient and the data related to the outcome will be kept confidential and the primary data will be stored in a separate file, protected with password for a period of 5 years.

OBSERVATIONS:

Sl no	Demographic data	Percentage
1	Age	30-40: 30% 41-50: 35% 51-60: 35%
2	Gender	Female: 55% Male: 45%
3	Religion	97.5% subjects were Hindu
4	Occupation	Prevalence of Farmers and workers were more i.e. 32.5% and 30% respectively
5	Education	Prevalence of undergraduates were more i.e. 65%
6	Marital status	Married: 95% Unmarried: 5%

7	Family history	77.5% of subjects had Negative family history
8	Diet	70% of subjects had mixed diet
9	Prakruti	40% of subjects had vata-pitta Prakruti
10	Pramana	90% of subjects had Madhyama Pramana
11	Sara	85 % subjects had Madhyama sara
12	Samhanana	95 % subjects had Madhyama Samhanana
13	Satva	67.5% had Madhyama Sharirika Satva 75% had Madhyama Manasika Satva
14	Sathmya	92.5% of subjects had Madhyama Sathmya
15	Abhyavarana shakthi	75% of subjects had Madhyama shakti
16	Jarana shakthi	87.5% of subjects had Madhyama shakti
17	Vyayama shakthi	70% of subjects had Madhyama shakti

RESULTS:

1. DAHA

Effect of Treatment on Daha within Group A

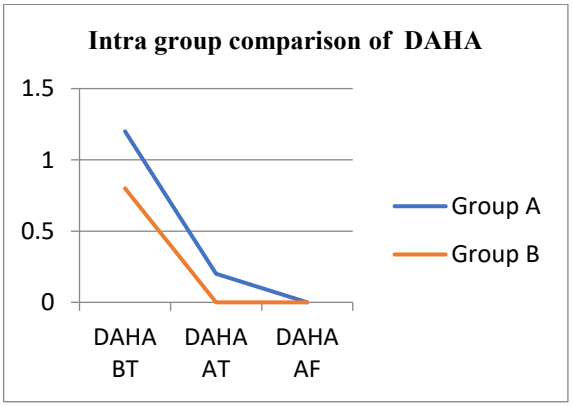
	N	Mean	Std. Deviation	Minimum	Maximum	Median	Mean rank	Chi-Square value	p value of Friedman Test
BT	20	1.20	0.696	0	2	1.00	2.85	32.109	0.000**
AT	20	0.20	0.410	0	1	0.00	1.68		
AF	20	0.00	0.000	0	0	0.00	1.48		

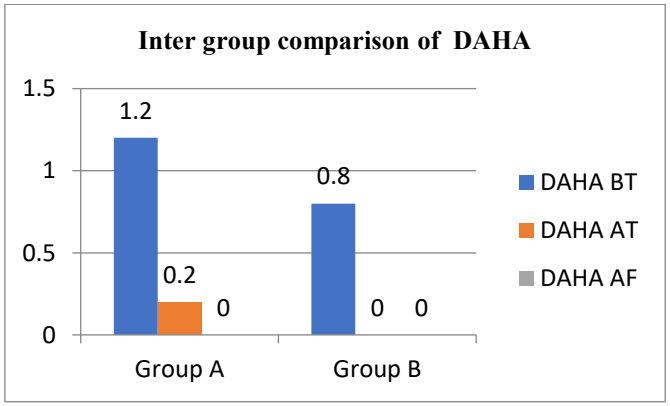
Effect of Treatment on Daha within Group B

	N	Mean	Std. Deviation	Minimum	Maximum	Median	Mean rank	Chi-Square value	p value of Friedman Test
BT	20	0.80	0.523	0	2	1.00	2.75	30.000	0.000**
AT	20	0.00	0.000	0	0	0.00	1.63		
AF	20	0.00	0.000	0	0	0.00	1.63		

Inter group comparison of Daha

Group		N	Mean	Std. Deviation	Mean Rank	Sum of Ranks	Median	Mann-Whitney U value	Z-value	p value of Mann-Whitney U test
BT	A	20	1.20	0.696	23.70	474.00	1	136.000	-1.975	0.048*
	B	20	0.80	0.523	17.30	346.00	1			
AT	A	20	0.20	0.410	22.50	450.00	0	160.000	-2.082	0.037*
	B	20	0.00	0.000	18.50	370.00	0			
AF	A	20	0.00	0.000	20.50	410.00	0	200.000	0.000	1.000#
	B	20	0.00	0.000	20.50	410.00	0			





2. GHARSHA

Effect of Treatment on Gharsha within Group A

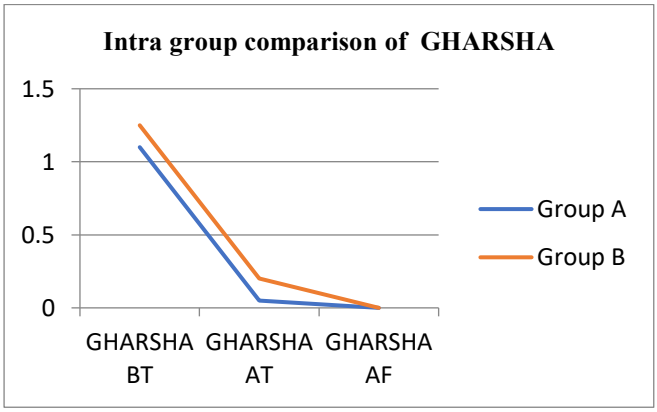
	N	Mean	Std. Deviation	Minimum	Maximum	Median	Mean rank	Chi-Square value	p value of Friedman Test
BT	20	1.10	0.308	1	2	1.00	3.00	39.377	0.000**
AT	20	0.05	0.224	0	1	0.00	1.53		
AF	20	0.00	0.000	0	0	0.00	1.48		

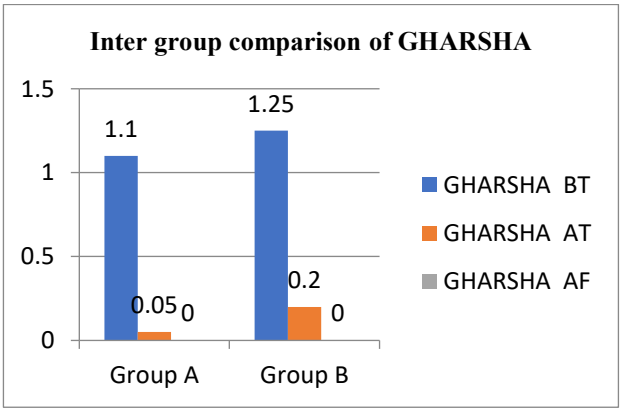
Effect of Treatment on Gharsha within Group B

	N	Mean	Std. Deviation	Minimum	Maximum	Median	Mean rank	Chi-Square value	p value of Friedman Test
BT	20	1.25	0.639	0	2	1.00	2.90	34.069	0.000**
AT	20	0.20	0.410	0	1	0.00	1.65		
AF	20	0.00	0.000	0	0	0.00	1.45		

Effect of Treatment on Gharsha between Group A &Group B

Group		N	Mean	Std. Deviation	Mean Rank	Sum of Ranks	Median	Mann-Whitney U value	Z-value	p value of Mann-Whitney U test
BT	A	20	1.10	0.308	18.90	378.00	1	168.000	-1.110	0.267#
	B	20	1.25	0.639	22.10	442.00	1			
AT	A	20	0.05	0.224	19.00	380.00	0	170.000	-1.416	0.157#
	B	20	0.20	0.410	22.00	440.00	0			
AF	A	20	0.00	0.000	20.50	410.00	0	200.000	0.000	1.000#
	B	20	0.00	0.000	20.50	410.00	0			





3. RAGA

Effect of Treatment on Raaga within Group A

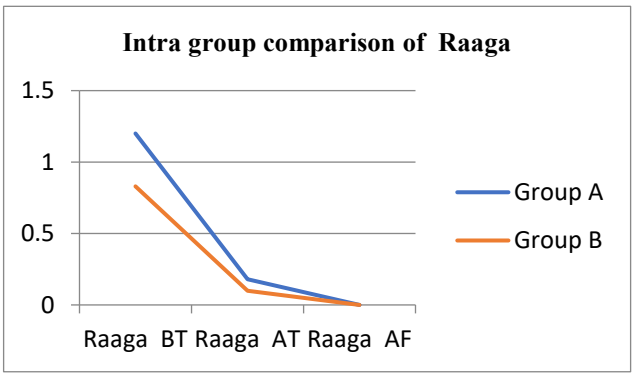
	N	Men	Std. Deviaton	Minium	Maximum	Median	Mean rank	Chi-Square value	p value of Friedman Test
BT	20	1.20	0.648	0	2	1.00	2.88	66.500	0.000**
AT	20	0.18	0.385	0	1	0.00	1.65		
AF	20	0.00	0.000	0	0	0.00	1.48		

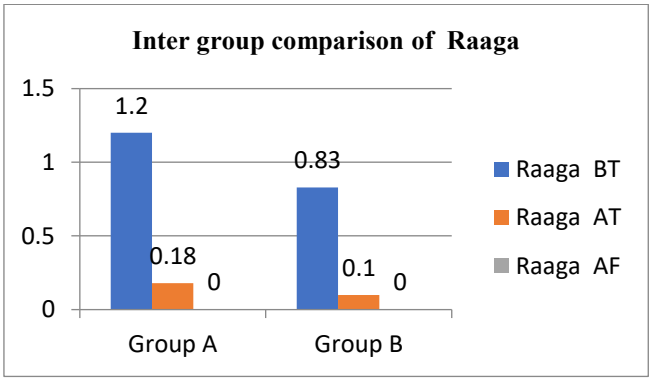
Effect of Treatment on Raaga within Group B

	N	Mean	Std. Deviation	Minimum	Maximum	Median	Mean rank	Chi-Square value	p value of Friedman Test
BT	20	0.83	0.594	0	2	1.00	2.73	55.802	0.000**
AT	20	0.10	0.304	0	1	0.00	1.69		
AF	20	0.00	0.000	0	0	0.00	1.59		

Effect of Treatment on Raaga between Group A &Group B

Group		N	Mean	Std. Deviation	Mean Rank	Sum of Ranks	Median	Mann-Whitney U value	Z-value	p value of Mann-Whitney U test
BT	A	20	1.20	0.648	46.46	1858.50	1	561.500	-2.599	0.009**
	B	20	0.83	0.594	34.54	1381.50	1			
AT	A	20	0.18	0.385	42.00	1680.00	0	740.000	-0.968	0.333#
	B	20	0.10	0.304	39.00	1560.00	0			
AF	A	20	0.00	0.000	40.50	1620.00	0	800.000	0.000	1.000#
	B	20	0.00	0.000	40.50	1620.00	0			





4. MAMSAVRIDDHI

The effect of treatment on length and width of Arma in the present study is not being subjected to statistical analysis as there was no changes observed in any patient however the change in the subjective and objective parameter where patient got benefit in Daha, Gharsha and Raaga can be justified with reduction in thickness of Arma.

Analysis of effect of treatment

It was observed that there was no statistically significant difference at baseline and after treatment ($p > 0.05$). In both groups, a highly significant difference was observed between BT (day 0) and AT (at 30th day) as $p < 0.05$.

DISCUSSION:

Selection of the Problem:

Arma, described in classical Ayurvedic texts under Shuklagata Netra rogas, closely corresponds to Pterygium- a fibrovascular proliferative growth of conjunctival tissue encroaching upon the cornea, with a global prevalence of 2–22%, particularly prevalent in tropical and subtropical populations exposed to chronic ultraviolet radiation, wind, and dust. Increasing urbanization, air pollution, and altered tear film dynamics have further contributed to its rising incidence. Conventional management relies primarily on surgical excision; however, recurrence rates following bare sclera excision remain as high as 30–80%, and even with adjunctive therapies such as mitomycin-C and conjunctival autografting, long-term outcomes are inconsistent. Ayurveda advocates Kriyakalpa procedures — particularly Anjana — for Netrarogas involving Kapha-Pitta vitiation, offering Lekhana, Shodhana, and Ropana actions directly at the conjunctival and corneal surface without the risks associated with surgical intervention. Shankanjana, a classical Anjana preparation with documented Lekhana and Kapha-Vata shamaka properties, presents a therapeutically rational candidate for the management of Arma.

Discussion on selection of drug: shankhanjana

Shankhanjana was selected based on its classical indication in Arma and its ability to address Kapha–Pitta predominance. Shankha Bhasma possesses Tikta–Kashaya Rasa, Laghu–Ruksha Guna, and Sheeta Virya, which help in Lekhana and Shoshana of fibrovascular growth. It also supports tissue healing through its Ropana property and calcium content. Madhu acts as a vehicle with Chakshushya, antimicrobial, and healing properties. Together, they help in reducing growth, promoting healing, and preventing recurrence.

Mode of action of Shankhanjana:

Shankhanjana acts by pacifying Kapha and Pitta through its Katu–Tikta Rasa and Sheeta Virya. Its Lekhana and Kshara-like action help reduce abnormal tissue growth in Arma. It also improves Rakta

quality, reducing redness, burning, and irritation. The calcium content aids in epithelial repair and tissue stabilization. Its anti-inflammatory and antimicrobial effects further support healing and prevent infection.

Discussion on analytical study

Analytical evaluation supports the therapeutic value of Shankhanjana. Organoleptic features like white colour and pungent odour indicate purity and active principles. Higher water-soluble extractive value shows good ocular bioavailability, while mild alkalinity supports Lekhana action. HPTLC profile confirms the presence of multiple bioactive compounds with antioxidant and anti-inflammatory properties. Overall, the formulation is stable, effective, and suitable for ocular use.

Discussion on observation:

Most patients belonged to the middle age group, suggesting prolonged exposure to environmental factors like dust, sunlight, and wind in the development of Arma. A slight female predominance was observed, but it holds no significant association. Higher incidence among farmers and workers highlights the role of outdoor exposure, while housewives may be affected due to indoor pollutants. Family history was absent in most cases, indicating minimal genetic influence. Vata–Pitta Prakrithi was predominant, supporting degeneration and inflammation in pathogenesis. Other factors like diet, Satva, Sara, and Vyayama Shakti showed no significant role in disease occurrence.

Discussion on Results

Both groups showed improvement in symptoms like Daha, Gharsha, and Raaga, though statistically non-significant. Reduction in Daha indicates Pittashamana effect, while improvement in Gharsha reflects Vata–Kapha balance. Decrease in Raaga suggests reduction in inflammation and vascular congestion. No change in Mamsavriddhi was observed due to its chronic structural nature. Overall, treatments were effective in symptom relief and controlling progression, with better response seen in Shankhanjana.

Scope for Future study

1. In the present study, cases with varied chronicity were included; however, in cases of 1–2 years duration, the length and width of Arma may reduce over a longer study period.
2. Long-term follow-up is needed to evaluate whether these formulations can prevent recurrence or slow down progression of the lesion
3. Anterior OCT can be adopted to measure the thickness of the pterygium which can be appreciated from the action of Lekhananjana .
4. Comparative trials with modern interventions (e.g., lubricants or anti-inflammatory drops) may provide a better understanding of the integrative potential of Ayurvedic management in pterygium.

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