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Evaluation of the combined effect of *Mahatriphaladi Ghrita Nasya, Tarpana,* Pana and *Rakta-mokshana* in *Adhimantha* (POAG)-An open Labelled Randomized Comparative Clinical Trial

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Abstract: *Adhimantha is a Sarvaakshigata Roga which involves the whole eye. it can be corelated to Glaucoma (POAG) as it is termed as a group of diseases. POAG is the sub-type of Glaucoma. Mahatriphaladi Ghrita was selected for clinical trial. The study comprises of 30 patients which were divided into two groups. In Group A ayurvedic treatment alongwith anti-glaucoma eye drops and in Group B only topical treatment was given. The patients were selected from OPD of Shalakya department of Patanjali ayurvedic hospital, Haridwar. These Patients were randomly selected, on the basis of inclusion criteria depending upon subjective and objective parameters with detailed clinical history. The duration of study was 90 days with 2 follow ups. In Group- A, 60.00% patients had moderate relief, 26.67% had Marked Improvement and 13.33% had mild Improvement. No patient was completely cured i.e.,0%. In Group- B, 46.67% patients had Moderate improvement, 53.33% patients had mild relief. No patient was completely cured i.e.,0%. The Overall effect of therapy showed no progression of the disease in the combined therapy group. No side effects was observed during the treatment.*

Key Words: *Adhimantha, POAG, Mahatriphaladi Ghrita, Nasya, Tarpana, Rakta-mokshana.*

1. INTRODUCTION:

Glaucoma comprises a range of eye conditions that can cause blindness. It ranks as the second leading cause of irreversible blindness globally and the third in India[1]. Detection and treatment pose significant challenges, with many cases going undetected. Glaucoma, including POAG, is considered under the category of *Adhimantha*[3]. In modern medicine, a wide range of topical and systemic anti-glaucoma medications are available[2]. These medications undoubtedly alleviate some of the symptoms associated with glaucoma. However, they come with their own limitations and potential side effects, necessitating careful consideration and monitoring during their use. Furthermore, exploring the integration of traditional medicine systems, such as Ayurveda, in the management of glaucoma may provide valuable insights and potential complementary treatment options. The holistic approach of traditional medicine systems may offer additional benefits in addressing the multifactorial nature of glaucoma and enhancing overall patient's well-being. The selection of *Mahatriphaladi Ghrita*[4] in glaucoma is based on its unique composition and beneficial effects on ocular health. The formulation primarily consists of potent herb and other herbs. These herbs possess antioxidant[5], anti-inflammatory, and neuroprotective properties, which contribute to the management of glaucoma. In the context of glaucoma treatment, *Mahatriphaladi Ghrita* can be administered through various routes, including *Tarpana*, *Nasya* and *Pana*. *Tarpana*[6] involves instilling the medicated ghee into the eyes, which helps nourish and lubricate the ocular structures, reduce intraocular pressure, and promote optic nerve health. *Nasya* refers to the administration of the ghee through the nasal passages[7], allowing the therapeutic components to reach the affected areas and provide systemic benefits. *Pana* which is Oral intake of *Mahatriphaladi Ghrita* enables the herbs to exert their effects internally, promoting overall eye health. The application of leeches in glaucoma primarily focuses on improving blood circulation

and reducing IOP. The leech stimulates localized bleeding and the release of their saliva, which acts as a natural anticoagulant and vasodilator[8]. This process enhances blood flow to the eye and surrounding tissues, potentially relieving the hypoperfusion often observed in glaucoma. Additionally, the anti-inflammatory properties of leech's saliva may help reduce ocular inflammation, protecting the optic nerve from further damage.30 patients were selected and randomly divided into two groups. In Group A the patients were given ayurvedic treatment together with topical antiglaucoma eye drops and in Group B patient received topical anti-glaucoma eye drops for 90 days.For this study,an attempt has been made to find cheap and effective treatment for glaucoma.

2. MATERIALS and METHOD: The study was approved by Institutional Ethical Commitee (IEC No.-PAC/IEC/2022/17) and CTRI registration (CTRI/2022/05/042635) was also done.Patients were selected from the O.P.D. of Dept. Of Shalakya. Treatment start only after getting the written consent. The study comprises of 30 patients which were divided into two groups. In Group A ayurvedic treatment alongwith anti-glaucoma eye drops and in Group B only topical treatment was given.

Inclusion criteria:

- Age 30 To 70 years.
- Patients of either sex.
- IOP < 20 mmHg with Glaucomatous changes and > 20mmHg corrected with CCT.
- Visual acuity more then 6/60 and clear media.

Exclusion criteria:

- Age <30 year and above 70 years.
- Visual acuity less than6/60.
- Secondary and developmental Glaucoma including exfoliative glaucoma, pigmentary glaucoma, trauma induced, inflammatory glaucoma, family history of glaucoma.
- Evidence of any anterior segment pathology like conjunctivitis, keratitis or acute uveitis.
- History of opaque ocular media (as in cataract, corneal opacities, vitreous opacities).
- Pregnant women.
- Any malignancy, uncontrolled diabetes, uncontrolled hypertension.
- People who are already registered under some other ongoing medical research.
- Contraindicated for Nasya.
- Contraindicated for Tarpana.
- Contraindicated for Rakta-mokshana (jalaukavcharana).

Proforma: A special proforma was prepared to maintain the records of all findings of the patients.

- **Subjective parameters**

1. Blurred vision
2. Frequent change of presbyopic glasses
3. Delayed dark adaptation
4. Visual field defect

- **Objective criteria**

1. Visual Acuity using Snellen's chart
2. IOP using Schiotz or Applanation Tonometry corrected with CCT
3. Direct and indirect ophthalmoscopic examination
4. Automated Perimetry
5. OCT-RNFL

Sample size: 30.

Grouping:

GROUP A: In this group the patient was given ayurvedic treatment together with topical antiglaucoma eye drop. The ayurvedic management consists of the following procedures:

1. ***Nasya***: It involves the transnasal application of 10 drops of *Mahatriphaladi Ghrita* in each nostril for the first 7 days in the morning. *Tarpana* was also given on the same day of *Nasya*.

2.***Tarpana***: It entails the application of *Mahatriphaladi Ghrita* in eye. It is performed for the first 7 days in the afternoon, with the quantity of *Mahatriphaladi Ghrita* adjusted as per the patient's requirements. Each session lasts for 25 minutes and the therapy was conducted alongwith *Nasya*.

3. ***Rakta-mokshana***: It is a bloodletting procedure which was been executed using leech on the 8th day in the afternoon, following prior blood investigations.

4. ***Pana***: For the next 22 days daily consumption of 6ml of *Mahatriphaladi Ghrita* mixed with milk was taken in the morning and evening.

The above procedures were performed for 1 month and then it was repeated in the same manner for the next two months. In this way, a total of three months were involved in the study.

Group B (Control group)

In this group, patient received topical anti-glaucoma treatment which consisted of Brimonidine 0.2% and Timolol 0.5%. The patients were under observation for three months to assess the effectiveness and tolerability of the medication in lowering intraocular pressure and managing glaucoma over the long term.

Dose and duration

Method involved	**Dose**	**Days**	**Time**
Nasya	10 *bindu* in each nostril	7 days	Morning
Tarpana	As per requirement of the patient upto sinking of eye lashes 1000 *Vakamatra kala* approx. 25 min	7 days	Afternoon
Rakta-mokshana	1-1 leech required	1 day	Afternoon
Pana	6 ml with warm water	22 days	Twice a day

Table no.1

Follow up

A follow-up assessment was conducted one month after the trial concluded, and this assessment was repeated for two consecutive months to monitor for any adverse effects or progression of symptoms.

Investigation: Haematological Examination (Hb%, LFT, RBS, HIV, HbsAg, HCV, CT/BT,) was done before treatment to rule out any systemic disease.

Grading:

Criteria	**Grading**	**Value**
Blurred Vision	Grade 0	No blurred vision
	Grade 1	Mild-Blurriness in vision but without restriction
	Grade 2	Moderate-Difficulty in performing routine work
	Grade 3	Severe-Unable to do things independently

Frequent changes in Presbyopic Glasses	Grade 0	Absent.
	Grade 1	Twice in a year with <3 months duration
	Grade 2	Thrice in a year
	Grade 3	Four times in a year

Delayed Dark Adaptation (DDA)	Grade 0	Adaptation to darkness within few seconds
	Grade 1	Slow dark adaptation within 10 seconds
	Grade 2	Slower dark adaptation within 20 seconds
	Grade 3	Slowest dark adaptation after 1 minute.

Visual Field Defect (VFD)	Grade 0	Absent
	Grade 1	Present

Best Corrected Visual Acuity (BCVA)	Grade 0	6/6 to 6/9
	Grade 1	6/9p -6/12p
	Grade 2	6/18 – 6/24
	Grade 3	6/24p – 6/36p
	Grade 4	6/60 - <6/60

Disk Hemorrhages (Splinter Hemorrhage)	Grade 0	Absent
	Grade 1	Present

Nasalization of Blood Vessels	Grade 0	Absent
	Grade 1	Present

Overall assessment:

Complete remission	100% relief
Marked improvement	≥75% to 99% relief
Moderate improvement	≥51% to 74% relief
Mild improvement	≥26% to 50% relief.
No improvement	up to 25% relief.

Statistical analysis

All information on various parameters was gathered and statistical study was carried out in terms of mean, standard deviation (S.D.), standard error (S.E.) and Wilcoxon signed pair rank test on the subjective parameters before and after treatment in both the groups. While Mann Whitney U test was applied to the statistical data for evaluating the difference in the effect of treatment on sign & symptoms. Unpaired t- test was applied to compare the objective data between both the groups and finally results were incorporated in terms of probability (p) as:

P >0.05	Not Significant
P<0.05	Significant
P <0.01	Very Significant
P <0.001	Highly Significant

3. OBSERVATION AND RESULTS:

In this clinical trial, there was 30 patients registered, and were randomly distributed into two groups. Among them 15 patients were registered in group A and 15 in Group B. No patients were dropout.

The general observation showen in fig.1

Chief complaints	Total %
Blurred vision	80%
FCPG	63.33%
DDA	86.67%
VFD	63.33%

In Group- A, 60.00% patients had moderate relief, 26.67% had Marked Improvement and 13.33% had mild Improvement. In Group- B, 46.67% patients had Moderate improvement, 53.33% patients had mild relief

Parameter	Eye	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value	Result
Blurred Vision	RE	Group A	15	17.43	261.45	85.000	0.00502	**Sig**
		Group B	15	13.57	203.55			
		Total	30					
	LE	Group A	15	16.96	254.40	91.500	0.00729	**Sig**
		Group B	15	14.04	210.60			
		Total	30					
FCPG	RE	Group A	15	16.46	246.90	97.500	0.00980	**Sig**
		Group B	15	14.54	218.10			
		Total	30					
	LE	Group A	15	16.86	252.90	93.000	0.00800	**Sig**
		Group B	15	14.14	212.10			
		Total	30					
DDA	RE	Group A	15	14.00	210.00	77.000	0.254	**NS**
		Group B	15	17.00	255.00			
		Total	30					

	LE	Group A	15	13.50	202.50	70.000	0.100	**NS**
		Group B	15	17.50	262.50			
		Total	30					
VFD	RE	Group A	15	17.00	255.00	77.000	0.072	**NS**
		Group B	15	14.00	210.00			
		Total	30					
	LE	Group A	15	17.00	255.00	77.000	0.072	**NS**
		Group B	15	14.00	210.00			
		Total	30					

Table no.2. Comparison between Group A and Group B (subjective)

Parameter	**Eye**	**Group**	**N**	**Mean Rank**	**Sum of Ranks**	**Mann-Whitney U**	**P-Value**	**Result**
BCVA	RE	Group A	15	15.93	238.93	92.000	0.608	**NS**
		Group B	15	15.07	226.07			
		Total	30					
	LE	Group A	15	16.00	240.00	91.000	0.549	**NS**
		Group B	15	15.00	225.00			
		Total	30					
VCDR	RE	Group A	15	16.00	240.00	91.000	0.317	**NS**
		Group B	15	15.00	225.00			
		Total	30					
	LE	Group A	15	15.96	239.46	91.500	0.578	**NS**
		Group B	15	15.04	225.54			
		Total	30					
MD	RE	Group A	15	16.46	246.96	84.500	0.435	**NS**
		Group B	15	14.54	218.04			
		Total	30					
	LE	Group A	15	18.32	274.82	58.500	0.084	**NS**
		Group B	15	12.68	190.18			
		Total	30					
GHD	RE	Group A	15	16.61	249.11	82.500	0.321	**NS**
		Group B	15	14.39	215.89			
		Total	30					
	LE	Group A	15	16.00	240.00	91.000	0.630	**NS**
		Group B	15	15.00	225.00			
		Total	30					

Table no. 3 Comparison between Group A and Group B on objective parameter

IOP	**Group**	**N**	**Mean Diff**	**SD**	**SE**	**t-Value**	**P-Value**	**Result**
RE	Group A	15	3.64	3.82	1.02	0.043	0.966	**NS**
	Group B	15	3.57	4.86	1.30			
LE	Group A	15	4.29	3.24	0.87	0.927	0.363	**NS**
	Group B	15	3.21	2.86	0.76			

Table no. 4 Comparison of IOP between Group A and Group B

Variable	Eye	Group	N	Mean Diff	SD	SE	t-Value	P-Value	Result
Superior Thickness	RE	Group A	15	8.64	10.89	2.91	2.384	0.0247	**Sig**
		Group B	15	1.43	3.11	0.83			
	LE	Group A	15	5.93	12.50	3.34	2.149	0.0411	**Sig**
		Group B	15	0.43	0.65	0.17			
Inferior Thickness	RE	Group A	15	5.86	13.24	3.54	2.144	0.0415	**Sig**
		Group B	15	0.64	1.28	0.34			
	LE	Group A	15	5.36	6.79	1.81	2.585	0.0157	**Sig**
		Group B	15	0.50	1.83	0.49			
Average RNFL Thickness	RE	Group A	15	5.43	7.36	1.97	2.313	0.0289	**Sig**
		Group B	15	0.86	0.77	0.21			
	LE	Group A	15	4.29	7.97	2.13	2.149	0.0411	**Sig**
		Group B	15	0.79	0.80	0.21			

Table no. 5 Comparison between Group A and B on Retinal nerve fibre thickness

4. DISCUSSION: *Ayurveda*, with its focus on prevention and cure through *Rasayana* and *Chakshushya* drugs, holds a promise in the integrated management of glaucoma. Ayurvedic treatments involve whole-body detoxification followed by targeted medications that may enhance tissue vitality and resistance to age-related and neurodegenerative diseases like glaucoma. The topic was selected to explore a cost-effective therapy that complements modern antiglaucoma treatments and addresses both IOP reduction and neuroprotection through *Ayurvedic* approaches. In the study maximum patients (66.66%) belonged to age group of 51-70 which shows high suspect on having POAG. Maximum patients were male (76.67) and Hindu (100%). Maximum patients were vata-kaphaja prakriti (46.67%) and maximum patients chronicity were 5 to 10 yrs (90%).all patients had bilateral affected eyes (100%).most of the patients had increased VCDR (87%).

Probable mode of action of *Nasya*

It is explained that the drug administered through the nostrils travels through the *Nasa Srota* (channels) and reaches *Sringataka*, a *Siramarma* (vital point) in the head. From there, it spreads to various parts including the *Murdha* (brain), *Netra* (eyes), *Shrotra* (ears), *Kantha* (throat), *Sira Mukhas*, and effectively removes the accumulated *doshas* in the *Urdwajatru* (upper part of the body).

The preoperative procedures, known as *Poorvakarma*, play a significant role in facilitating the entry of the drug into the body. Lowering the head, elevating the lower extremities, and applying heat to the face can impact the blood circulation in the head and face. The superficial surface of the face contains efferent vasodilator nerves, which can be stimulated by heat application, leading to increased blood flow to the brain.

Initially, it was believed that lowering the head was crucial for the medicine to reach the sinus ostia. However, subsequent studies demonstrated that instilling drops into the nose while in a head-downward position is the most effective way to decongest the sinuses. The head-down and forward position has been found to be the most effective based on radiological studies and supported by clinical trials.

Once the drug is absorbed, it can follow neural pathways (olfactory and trigeminal) and circulatory pathways (cavernous sinus) to reach the target site of action. It can influence various levels, including the limbic system (psychic level), sensory level, motor level (Trigeminal nerve), and general circulation, ultimately producing its desired effects, whether it be excitation or sedation. After the *Nasya* procedure, it is recommended to massage the frontal, temporal, maxillary and mastoid regions. This gentle massage can help alleviate any irritation caused by the medicine.

Probable Mode of Action of *Tarpana*

The mechanism of action of *Tarpana* can be understood in the light of modern pharmacology. Here the mucosal membranes and occular blood vessels acts as the absorbing surfaces. For a drug to be absorbed through mucus membranes and corneal layers, it should be both hydrophilic and lipophilic. In suspension, drug is present as small particles suspended in liquid medium by a dispersing agent (medicated *Sneha*). The drug contact time has effect upon

the absorption and penetration of drugs. Increased vascularity by local massage and pressure of the fluid on the ocular surface enhances drug absorption[9.]

Probable mode of action of *Rakta-mokshana* (*Jalauka*)
Leech saliva contains specific chemical constituents, including hirudin, hyaluronidase, and hematine. Hirudin functions as a potent thrombin inhibitor, displaying anticoagulant properties by interfering with the blood clotting process. Hyaluronidase, an enzyme present in leech saliva, targets and degrades hyaluronic acid, a crucial component of connective tissue, promoting enhanced blood flow in the affected area.

5. RECOMMENDATIONS: Studies can be performed with large sample size and for long duration to get more promising results.

6. CONCLUSION: From the observations and results which were obtained from this study it can be concluded that: *Adhimantha* is a *sarvaakshigata roga* which involves the whole eye like *mandala* & *patala*. In the same way, it can be corelated to glaucoma (POAG) as it is termed as a group of diseases which involves the anterior segment as well as the posterior segment of eye. The pathology occurs in the anterior segment and the posterior segment shows the damage of the retinal nerve fibre, optic nerve & lamina cribrosa. POAG is the sub-type of glaucoma.The clinical study establishes that Ayurvedic treatment protocol of *Mahatriphaladi Ghrita Nasya, Tarpana, Pana and Raktamokshana* for POAG in Group A was found to be more effective. The *chakshusya* and *rasayana* properties of *Mahatriphaladi Ghrita* plays a significant role in *Agnimandhya, Margavarodha, Pranavaha, Rasavaha* and *Raktavaha Srothodushti* and *Vyadhikshamatwahani. Mahatriphaladi Ghrita nasya, Tarpana, Pana and Raktamokshana alongwith* modern Anti-glaucoma eye drops have an added effect in delaying the progression of Primary Open Angle Glaucoma.No side effects were observed during the treatment.

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