



A Systematic Review Of Clinical Trials For *Adhimantha* (Glaucoma).

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Abstract

Adhimantha is a term rooted in *Ayurveda*, classified as *Sarvagat Netrarogas* by *Acharya Sushruta* and *Vagbhat*. It originates from the Sanskrit words "Adhi" (intense) and "Mantha" (churning), symbolizing a deep, grinding pain sensation. Ayurvedic texts describe *Adhimantha* as a severe eye disorder caused by imbalances in the three doshas—*Vata*, *Pitta*, and *Kapha*. The predominant *Dosha* influences the symptoms, causes, and treatment approaches. It is primarily characterized by "*Nayane Tivra Vedana*" (intense pain and inflammation) and "*Netram Nirmathyate Vedana*" (churned-up pain) in and around the eyes. *Adhimantha* presents symptoms similar to Glaucoma; a condition marked by raised intraocular pressure that can lead to pain and visual loss if left untreated. The burden of glaucoma worldwide was over 60.5 million people in the year 2010 and was estimated to be 80 million by 2020. Out of 39.36 million blind people globally, more than 3 million are blind due to glaucoma. Early detection is crucial for halting progressive visual impairment in glaucoma patients, as of now, treatment options remain limited, with no cure available. Several clinical trials within the AYUSH system have been registered with the Clinical Trial Registry-India (CTRI), highlighting the potential of ayurveda as a complementary path for future eye care research. This article critically examines the topic to deepen understanding and encourage well-informed discussions.

Materials & method

All Clinical trials registered with CTRI were searched using keywords like Glaucoma and *Adhimantha*. Apart from these AYUSH / Ayurveda/ Naturopathy/siddha / Unani / Homeopathy in different stages were also searched. These results were analysed and presented in terms of general characteristics of study, preventive trials, etc.

Result

There are a total of 16 studies which were analysed. Most of these studies are registered from ayurveda stream (n=12) and only 4 studies from Yoga & Naturopathy Stream. AYUSH study settings were utilized in 16 Studies. Only two studies have been done as a preventive trial. Studies conducted at single location are more in number. Most of these studies are from Delhi (n=7). Maximum studies conducted in age group between 30-70 years of age (n=7).

Conclusion

The present study is an attempt to review the CTRI – registered glaucoma clinical trials, which show the general characteristics of trials along with study design and setups. the contribution of AYUSH can be highlighted through this review.

Keywords

Glaucoma, Ayurveda, CTRI, Preventive Studies.

Introduction –

Adhimantha is a term described in *Ayurveda* that corresponds to severe ocular disorders, often co-related to glaucoma in modern ophthalmology¹. It is categorized as one of the *Sarvagata Netra Rogas*² (diseases affecting the entire eye) and is characterized by '*Netram Nirmathyate Vedana*'³, '*Ardhashiraso Vedana*'³, '*Rupam Pashyati Dukkhenā*'⁴. *Ayurvedic* texts describe four types of *Adhimantha* based on predominance of *Doshas*⁵ —*Vataja*, *Pittaja*, *Kaphaja* and *Sannipataja*—each associated with specific *Dosha* imbalance and corresponding symptoms. The acute nature and visual impact of *Adhimantha* in its clinical presentation closely resemble a glaucomatous condition. In *Ayurveda*, the pathophysiology of *Adhimantha* is attributed to vitiated *Vata* and *Pitta Doshas*, resulting in elevated ocular pressure, nerve degeneration, and vision loss. Traditional treatment methods encompass *Shodhana* (purification therapies), *Shamana* (palliative treatments), and *Netra Kriyakalpa* (topical ocular procedures), aiming to restore *Doshic* balance, relieve symptoms, and protect vision.

Glaucoma, often referred to as the 'silent thief of sight,' is a progressive and irreversible eye condition that impacts millions worldwide. It is a leading cause of permanent vision loss, affecting approximately over 60.5 million people in the year 2010 and was estimated to be 80 million by 2020.⁶ Out of total of 39.36 million blind people globally,⁷ more than 3 million are blind due to glaucoma⁸. Glaucoma is a complex optic neuropathy characterized by the gradual deterioration of the optic nerve.⁹ The condition primarily affects the optic nerve, which transmits visual signals from the retina to the brain. Various forms of glaucoma contribute to the degeneration of the retinal nerve fibre layer. A key factor in the disease's progression is the role of aqueous humour, the fluid that fills the anterior chamber of the eye. This fluid maintains intraocular pressure (IOP), nourishes ocular tissues, and drains through the pupil, trabecular meshwork, Schlemm's canal, and ultimately into the venous circulation. When an imbalance arises between aqueous humour production and drainage, IOP increases, often fluctuating significantly throughout the day¹⁰. Persistently elevated pressure can lead to the loss of nerve fibres, resulting in the characteristic "cupping" or concave appearance of the optic nerve head, observable during fundoscopy.⁹

In modern medicine, glaucoma treatment primarily involves topical medications, followed by systemic drugs and, ultimately, surgery.⁹ These approaches focus mainly on controlling intraocular pressure (IOP) but do not halt disease progression. In contrast, *Ayurvedic* management aims to slow disease progression, improve vision, and provide symptomatic relief to the patient.

With the increasing interest in integrative approaches to ocular diseases, research on *Adhimantha* and its correlation with glaucoma is becoming increasingly important. Scientific validation of *Ayurvedic* therapies through clinical trials and translational research can provide valuable insights into holistic and preventive eye care. This study examines the clinical presentation, pathophysiology, and treatment strategies for *Adhimantha*.

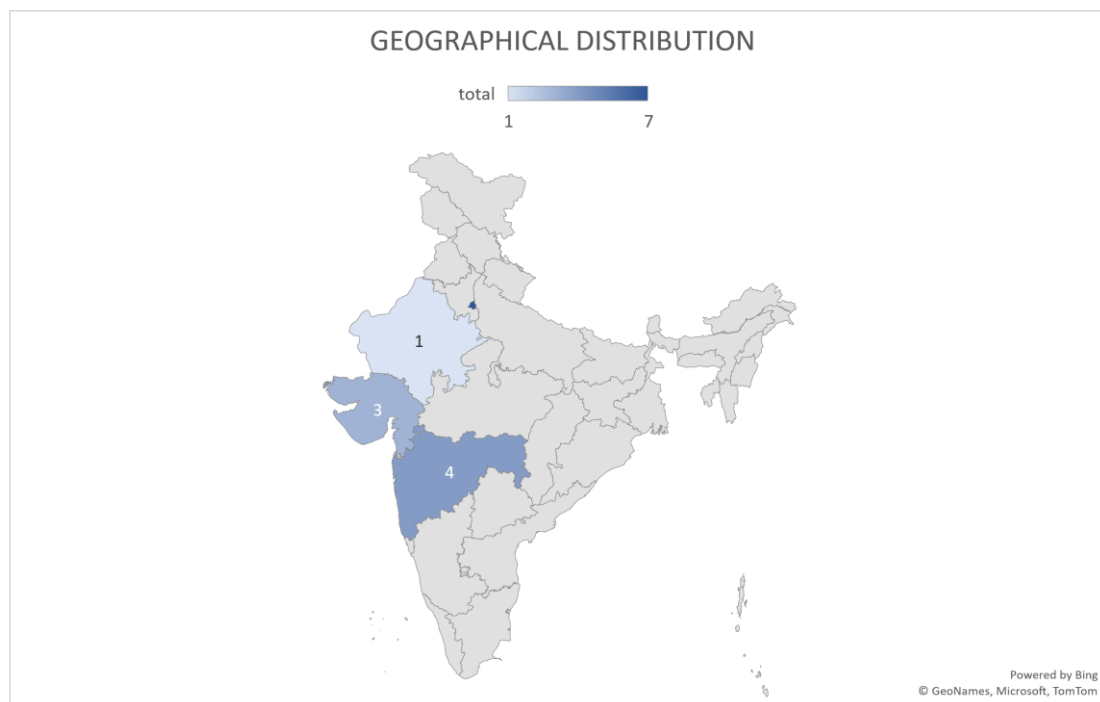
The current critical review aims to evaluate the characteristics of AYUSH studies registered in the Clinical Trial Registry - India (CTRI). By analysing their methodologies and *Ayurvedic* management approaches, this review seeks to provide valuable insights for future researchers.

Methods

All clinical trials for *Adhimantha* (glaucoma) enrolled with CTRI, between December 2014 to September 2024 were recovered utilizing keywords like glaucoma/ *Adhimantha*/ *Sarvagat Roga*. Apart from these, AYUSH/ *Ayurveda* / Naturopathy / Siddha / Unani / Homoeopathy in different stages and blends were also searched. Those trials that are registered with CTRI are considered as **inclusion criteria** for the study while those that are not registered with CTRI but registered with other registries are excluded. The initial creators retrieved the information autonomously and cross-examined it to check for errors. The gathered information was embedded in book keeping pages according to different things of the CTRI enrolment data set. At first, the investigation was examined by general qualities like month of enrolment, points of study, study settings, destinations, etc. They were classified according to the contemplated plan (observational/ interventional). All investigations were dissected regarding sample size, study population, medication, comparators, treatment length, study span, and result measures. These information qualities are introduced as actual numbers.

Result -

We studied 16 trials from AYUSH systems related to adhimantha (glaucoma) that were registered with CTRI during the review. Out of 16 studies 12 studies are from ayurveda stream and only 4 from yoga and naturopathy stream. The records said that these studies were conducted at 15 sites. No study was found on Homeopathy. As per geographical distribution, the maximum number of sites are in Delhi [n-7] followed by Maharashtra [n-4], Gujrat [n-3], Uttaranchal [n-1], Rajasthan [n 1]. *Figure 1*



General characteristics of the registered studies-

Reviewing these studies system-wise it is found that studies from Ayurveda are higher [n-11] than the other systems. There were only 4 trials from yoga and naturopathy stream and 0 trials from homeopathy stream. All the studies were interventional type of studies. The interventional studies were further classified as per their aim, prevention [n-2] and recovery [n- 13]. All studies were carried out on a single site. It is found that a major number of studies were sponsored by Government funding agencies / Government Institutions / Government Colleges [n – 12] as compared to investigator-initiated studies. Out of 15 studies collected from CTRI, Private Colleges / Institutions funded were 04. There were 7 studies with a population aged between 30 - 70 years while 2 studies included individuals from 40-70 years. Two studies included 18-60 years of age and only 2 studies included individual above age of 80 years and 90 years. It is observed that single arm study is only one, randomised parallel group active controlled trial were 7 in number, randomised parallel group trial were 6 and randomised parallel group placebo-controlled trial was only one.

As all the studies were interventional, we divided them into prevention and recovery types of studies according to their aim. All these studies were analysed concerning different characteristics like sample size, study population, type of intervention, comparator, duration of treatment, duration of study, and outcome of study.

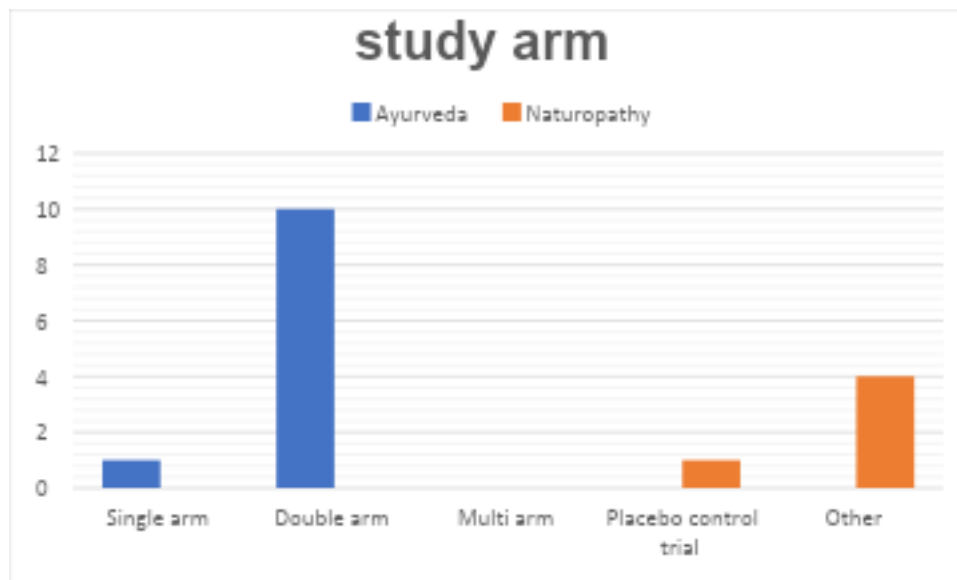
Preventive studies [n – 2]

A total of 02 studies were planned for the prevention of glaucoma. One study was a single-arm study as there was no comparator, another study was double-arm. In the double-arm study, there was a comparison between AYUSH treatment and conventional care was done. One study had a sample size of 20, while the other has 36. All preventive studies [n-2] had multi-drug formulations. The treatment duration ranges from seven days to nine months. The study duration is from one year six months to two years. As these studies were preventive, the primary outcome was prevention of the ganglionic cell loss in primary open angle glaucoma while showing relief from clinical signs and symptoms and improvement in visual field defects was seen as a secondary outcome. In the other study, to evaluate adjuvant effect of therapy and medication on symptoms was the primary outcome effect on visual symptoms was the secondary outcome.

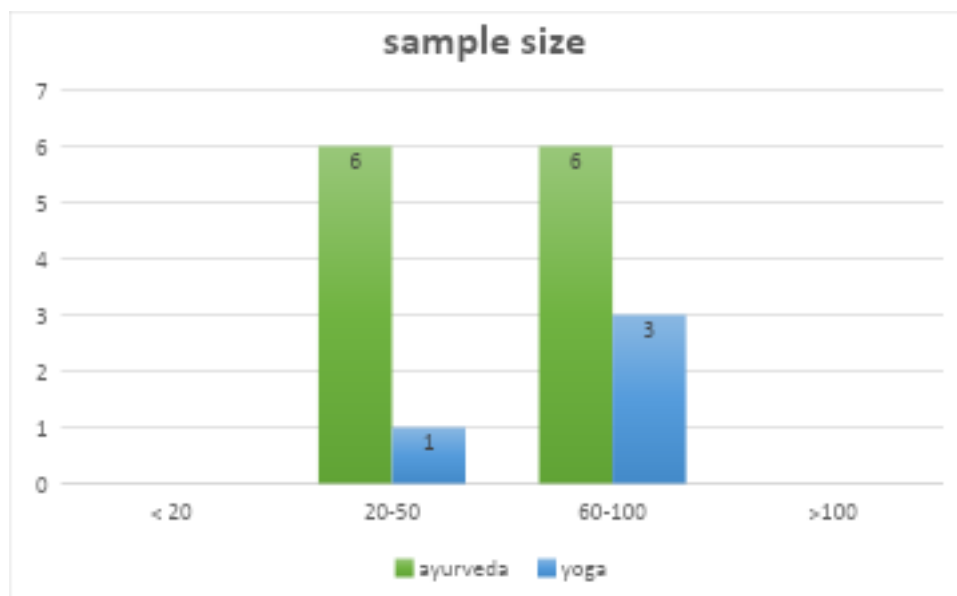
Many studies including age group in different manner. but most of the studies have age group between 30-70 years of age. this study includes year wise classification

Year	No. of studies
2013	1
2014	10
2016	3
2017	1
2018	1
2019	1
2020	2
2021	2
2022	1
2023	1
2024	2

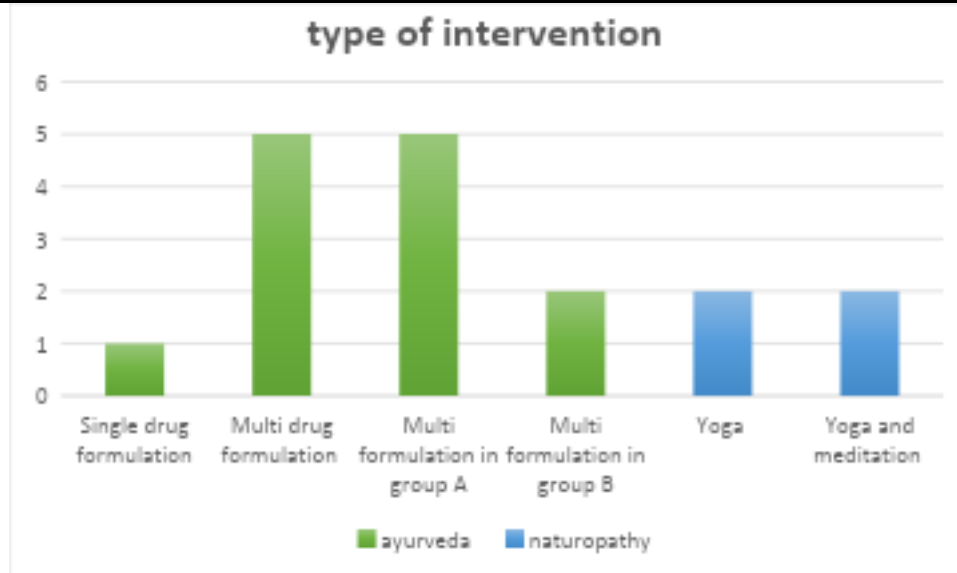
Table 1 year wise distribution



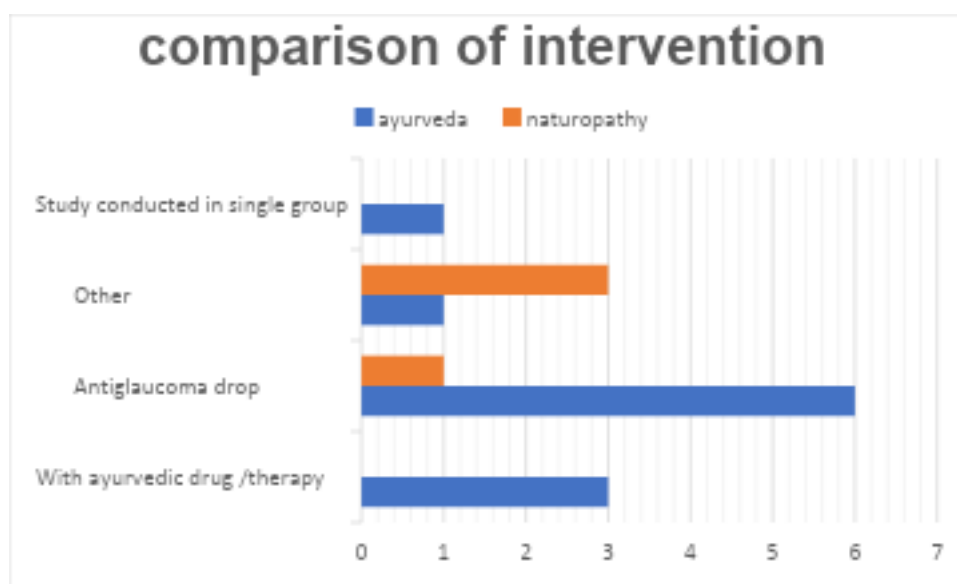
Graph 1 study arm



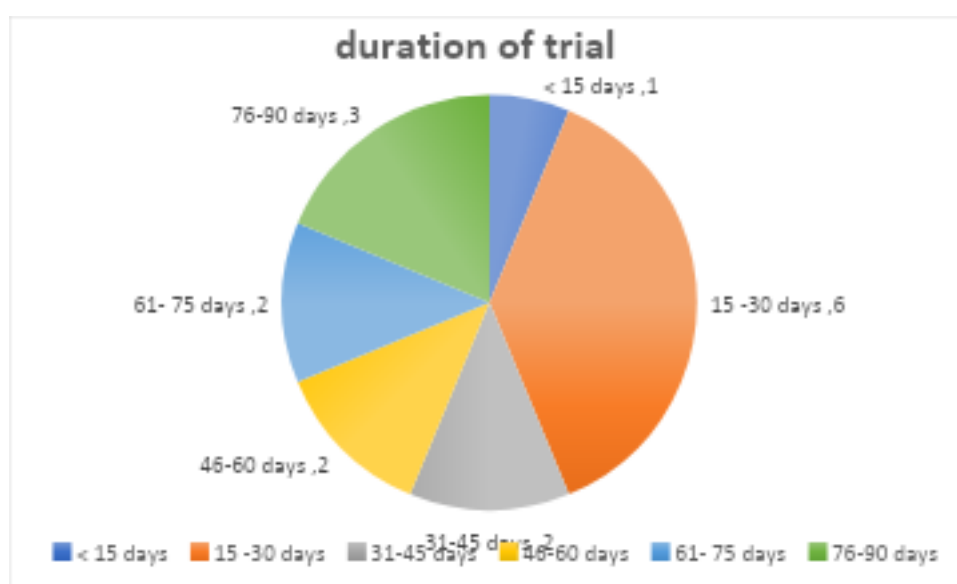
Graph 2 sample size



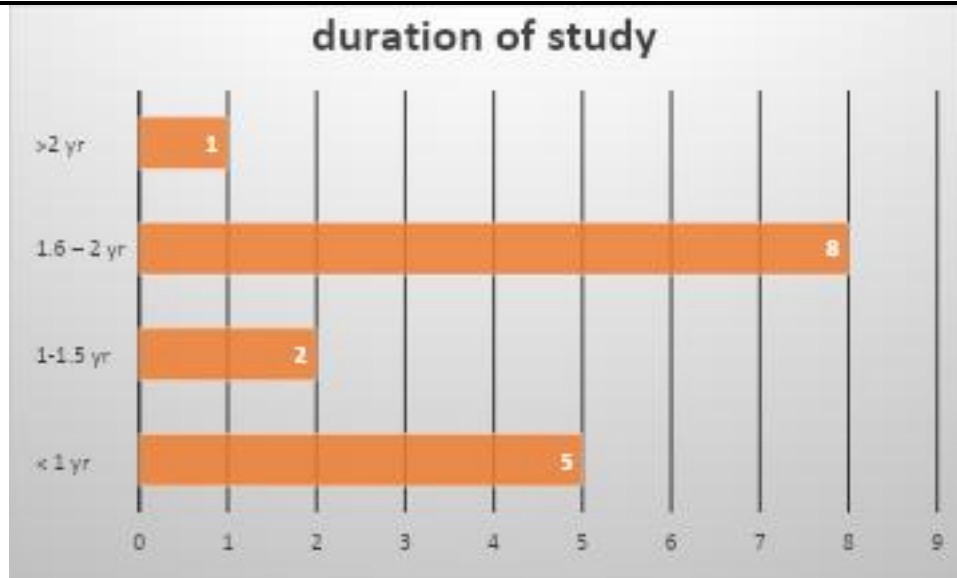
Graph 3 type of intervention



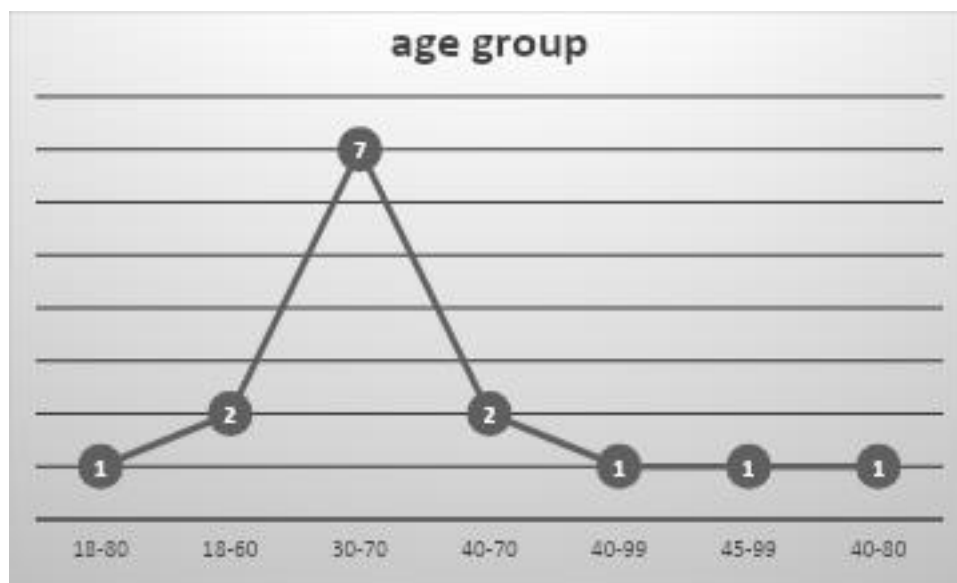
Graph 4 comparison of intervention



Graph 5 duration of trial



Graph 6 duration of study



Graph 7 age group

Characteristics of study	Ayurveda	Percent age	Naturopathy	Percentage
Study arm				
Single arm	1	6.25%	0	0%
Double arm	10	62.5%	0	0%
Multi arm	0	0%	0	0%
Placebo control trial	0	0%	1	6.25%
Other	0	0%	4	25%
Sample size				
< 20	0	0%	0	0%
20-50	6	37.5%	1	6.25%
60-100	6	37.5%	3	18.75%
>100	0	0%	0	0%

Type of intervention				
Single drug formulation	1	6.25%	0	0%
Multi drug formulation	5	31.25%	0	0%
Multi formulation in group A	5	31.25%	0	0%
Multi formulation in group B	2	12.5%	0	0%
Yoga	0	0%	2	12.5%
Yoga and meditation	0	0%	2	12.5%
Comparison of intervention				
With ayurvedic drug /therapy	3	18.75%	0	0%
With allopathic drug/therapy				
Antiglaucoma drop	6	37.5%	1	6.25%
Other	1	6.25%	3	18.75%
Study conducted in single group	1	6.25%	0	0%

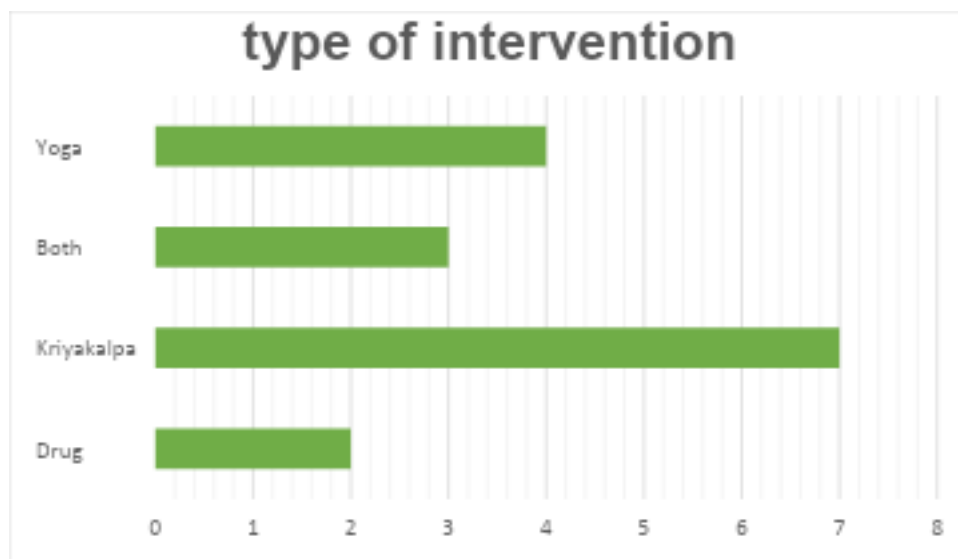
Table 2 general characteristics

State wise distribution of adhimantha in the study –

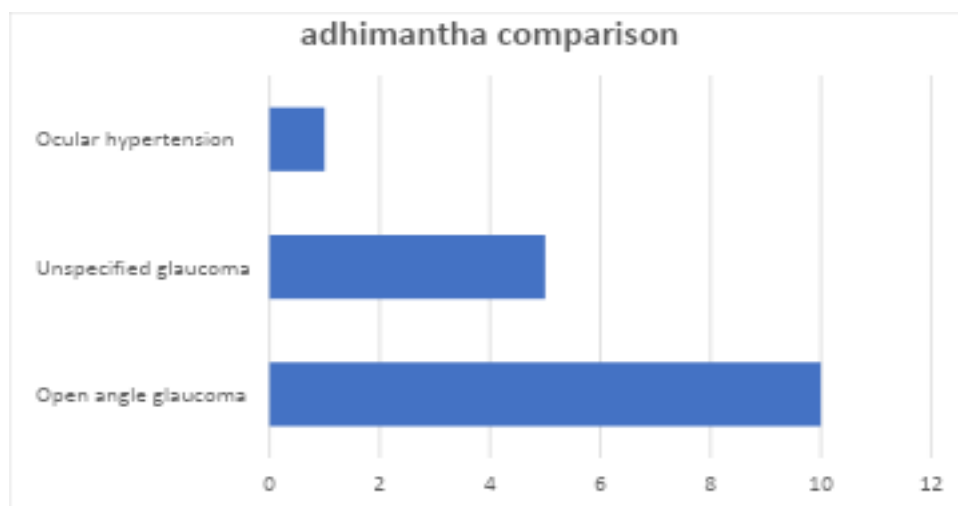
Sr no	STATE	Total study done in each state (n)	Percentage
1	Maharashtra	4	25%
2	Gujrat	3	18.75%
3	Delhi	7	43.75%
4	Rajasthan	1	6.25%
5	Uttaranchal	1	6.25%
	DURATION OF TRIAL	TOTAL	Percentage
1	< 15 days	1	6.25%
2	15 -30 days	6	37.5%
3	31-45 days	2	12.5%
4	46-60 days	2	12.5%
5	61- 75 days	2	12.5%
6	76-90 days	3	18.75%
	DURATION OF STUDY	Total	Percentage

1	< 1 yr	5	31.25%
2	1-1.5 yr	2	12.5%
3	1.6 – 2 yr	8	50%
4	>2 yr	1	6.25%
	AGE GROUP		
1	18-80	1	6.25%
2	18-60	2	12.5%
3	30-70	7	43.75%
4	40-70	2	12.5%
5	40-99	1	6.25%
6	45-99	1	6.25%
7	40-80	1	6.25%

Table 3 state wise distribution

Details of ayurveda studies –

Graph 8 type of intervention



Graph 9 adhimantha comparison

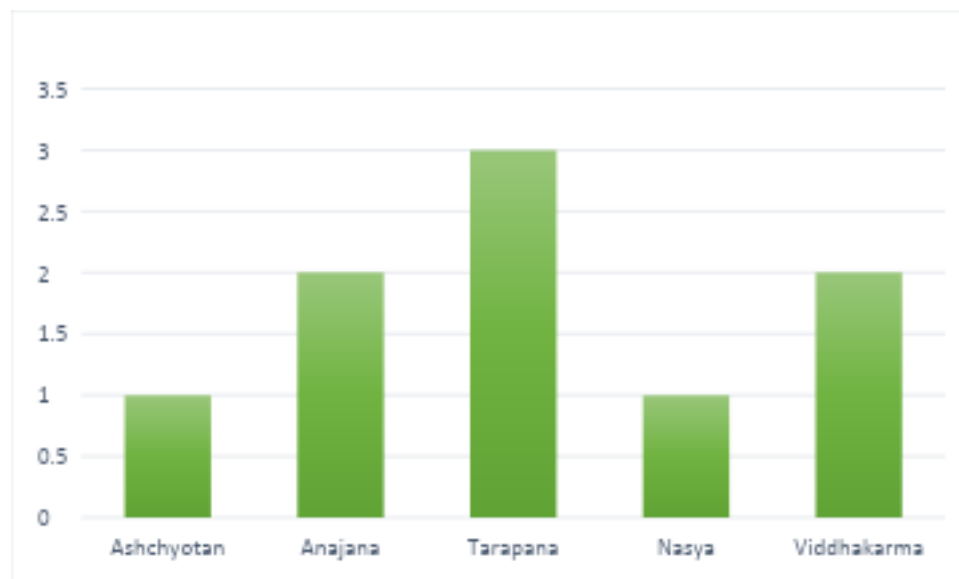
Type of intervention	Frequency	Percentage
Drug	2	12.5%
Kriyakalpa	7	43.75%
Both	3	18.75%
Yoga	4	25%
Adhimantha comparison in study	Total	
Open angle glaucoma	10	62.5%
Unspecified glaucoma	5	31.25%
Ocular hypertension	1	6.25%

Table 4 type of intervention

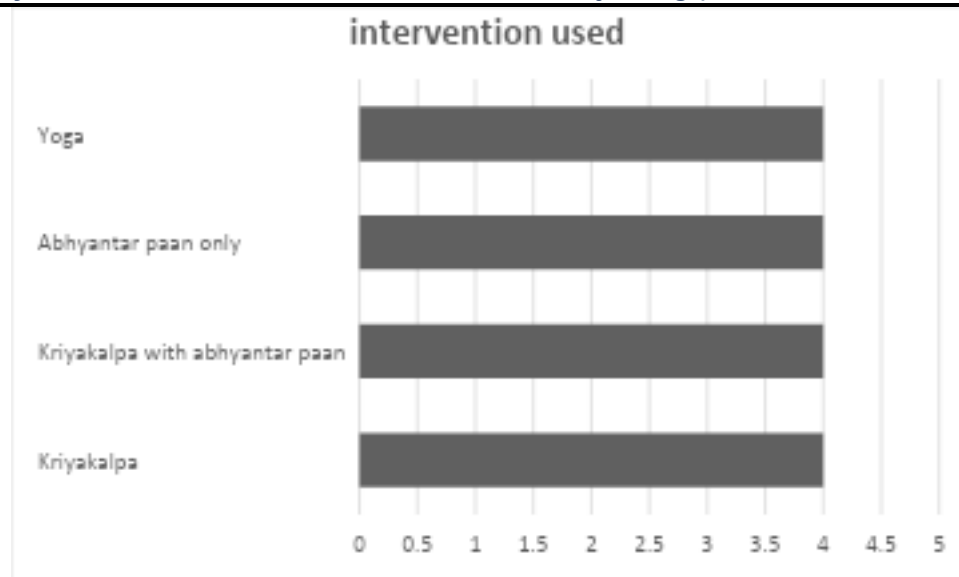
Details of intervention

Sr no.	Details of intervention	Frequency	Percentage
1	Ashchyotan	1	6.25%
2	Anajana	2	12.5%
3	Tarapana	3	18.75%
4	Nasya	1	6.25%
5	Viddhakarma	2	12.5%
	Intervention used		
	Kriyakalpa	4	25%
	Kriyakalpa with abhyantar paan	4	25%
	Abhyantar paan only	4	25%
	Yoga	4	25%

Table 5 details of intervention



Graph 10 frequency



Graph 11 intervention used

Sr no	Details of intervention	Frequency	Percentage
1	Amalaki Rasayan	1	6.25%
2	Nagaradi ashchyotan	1	6.25%
3	Viddhakarma	2	12.5
4	Vati		
	Rasayan vati	1	6.25%
	Chandraprabha vati	1	6.25%
	Punarnavagokshur ghanvati	1	6.25%
	Gokshuradi guggul	1	6.25%
5	Ghrita		
	Panchatikta	1	6.25%
	Triphala	1	6.25%
	Mahatriphaladi	1	6.25%
6	Anjana		
	Swarnagairikadi gutika Anjana	2	12.5%
7	Nasya		
	Jeevantyadi tail	1	6.25%
8	Tarpana		
	Goghrita	1	6.25%
	Shigru Pallav arka	2	
9	Varaforte powder	1	6.25%
10	Punarnavshtak kwath	1	6.25%
11	Yoga	3	18.75%
12	Meditation	2	12.5%

Table 6

● Study Characteristics

1. Study Type: All 16 studies were interventional.
2. Study Design: Maximum studies (n=15) were double-arm studies.
3. Comparison: Ayurveda interventions were compared with conventional care in 15 studies.
4. Sample Size: Most studies (n=10) had a sample size ranging from 30-70

5. Interventions: Studies involved multidrug formulations and multi-formulation regimens.

● Study Duration and Population

1. Study Duration: 10 studies had a duration of 1 year to 1 year 6 months, while 5 studies had a treatment span of below 30 days.
2. Population Age: Most studies (n=7) involved populations between 30-70 years old.
3. Age Distribution: No studies involved populations under 18 years, while 4 studies involved populations above 70 years.

● Ethics and Registration

1. Ethics Committee Approval: All studies registered with CTRI had approval from the Ethics Committee.
2. Assumption: It is assumed that ethics related to age groups were adequately taken care of by respective committees.

Overall, this analysis provides insight into the characteristics of Ayurveda studies on adhimantha, highlighting the prevalence of interventional studies, double-arm designs, and comparisons with conventional care.

Discussion-

Adhimantha, as described in Ayurveda, closely resembles the clinical manifestations of glaucoma in modern ophthalmology. Classical Ayurvedic texts categorize Adhimantha into four types based on doshic involvement—Vataja, Pittaja, Kaphaja, and Sannipataja—each presenting symptoms that correlate with different forms of glaucoma.

1. Pathophysiology and Comparison with Glaucoma

Ayurvedic Perspective: Adhimantha is considered an acute or chronic disease affecting the eye, primarily caused by imbalances in Vata, Pitta, and Kapha doshas. Symptoms like pain, pressure sensation, redness, lacrimation, and blurred vision align with modern descriptions of increased intraocular pressure (IOP) in glaucoma.

Modern Perspective: Glaucoma is a progressive optic neuropathy characterized by elevated IOP, optic nerve damage, and visual field loss. While Ayurvedic texts do not explicitly mention IOP, they describe symptoms like heaviness, dimness of vision, and visual distortions, which align with glaucoma's pathophysiology.

2. CTRI-Registered Clinical Trials on Adhimantha and Glaucoma

Very few studies have been conducted on Adhimantha, and even fewer are registered with the CTRI. The limited availability of modern equipment across Teaching institute poses a challenge in research and diagnosis. There is a need to shift perspectives on this disease, emphasizing the integration of Ayurveda as a supportive treatment alongside modern medicine to enhance patient care.

Key findings include: Ayurvedic therapies like swarnagutikadi Anjana, triphala ghrita, and Netra Tarpana (therapeutic oil retention on the eye) have shown potential in symptomatic relief and visual improvement. Some trials indicate improvement in subjective symptoms such as eye strain, coloured halos, and headache, but objective glaucoma markers remain largely unchanged.

Comparative analysis with modern anti-glaucoma treatments (like timolol eye drops) suggests that while Ayurvedic therapies provide supportive management, they may not be sufficient as standalone treatments.

3. Strengths and Limitations of Ayurvedic Management

Strengths:

- Ayurvedic formulations often contain antioxidant and neuroprotective properties (e.g., Triphala, Yashtimadhu) that may support optic nerve health.
- Minimal side effects compared to synthetic drugs, making them a potential adjunct therapy.

- Holistic approach, addressing systemic factors like stress, digestion, and overall eye health.
- Rasayan (Rejuvenation) therapy – helps in neuro protection, slowing in optic nerve degeneration and improving retinal health.

Limitations:

- Lack of evidence for IOP reduction, a crucial factor in glaucoma management.
- Need for longer follow-up periods and larger sample sizes in clinical trials.
- Absence of standardized equipment's and diagnostic tools.

4) Future Scope and Research Directions

More randomized controlled trials (RCTs) with larger participant groups are needed to evaluate the efficacy of Ayurvedic treatments. Integration of biochemical and imaging studies (e.g., optical coherence tomography) can provide objective assessments of optic nerve protection. A multimodal approach, combining modern and Ayurvedic therapies, may be beneficial for long-term glaucoma management.

Conclusion

This study reveals that 87.5% of the research focuses on Ayurveda, while only 25% pertains to Yoga and Naturopathy. The majority of studies (62.5%) were conducted in 2014, followed by 18.75% in 2016. Only two studies were dedicated to prevention. Notably, Yoga was the most frequently used intervention, appearing in 18.75% of the studies. While Ayurveda offers valuable insights into symptom management and overall ocular health, current evidence indicates that Ayurvedic treatments for Adhimantha should be used as a complementary approach alongside primary glaucoma therapy. Continued research is required to bridge the gap between traditional wisdom and modern ophthalmology, ensuring evidence-based integration for optimal patient outcomes. Further research, particularly randomized controlled trials with larger sample sizes and longer follow-up periods, is necessary to comprehensively evaluate the efficacy and safety of Ayurvedic interventions in the management of glaucoma. Modern medicine offers effective IOP-lowering agents, whereas Ayurveda excels in neuroprotective, anti-inflammatory, and rejuvenate therapies that aid in slowing disease progression and enhancing overall eye health. Integrating Ayurveda with modern glaucoma management could offer a complementary and sustainable approach in preventing vision loss.

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