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Effect of Ayurveda protocol (*Nasya, Pindi, Bidalaka & Anjana*) in Intra Ocular Hydrops – A Pilot Study

Research Article

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Abstract

Introduction: Normal Intra Ocular Pressure (IOP) ranges from 14 – 21 mm of Hg. Intra-Ocular Hydrops is an asymptomatic condition with raised Intra Ocular Pressure without any visual impairment or comorbidities. Altered Intra Ocular Pressure above / below normal level with associated visual symptoms & optic neuropathy are referred to as glaucoma. Intra Ocular Hydrops population is at greater risk of developing glaucoma. They remain unnoticed and undiagnosed most of the time for a longer duration or advancement of the condition. Early diagnosis and timely management prevent the progression of the disease to Primary Open Angle Glaucoma and other conditions. Proven Ayurvedic treatment modalities are not available for Intra Ocular Hydrops. In such a scenario, considering the multifactorial involvement, an Ayurvedic protocol containing different treatment modalities was developed and its effect was studied. Materials & Methods: 300 patients were screened from the eye Out Patient Department of institute. 10 Patients who fulfilled the inclusion criteria were enrolled and analysed for results. *Ayureda* Protocol was administered (Table 1) which included an In Patient Department basis for *Nasya*, *Pindi* and *Bidalaka* for a period of 11 days and Anjana for a period of 30 days. The assessment of Intra Ocular Pressure was done with the help of Goldman's Applanation Tonometry. The assessment was done on 0th day (Before Treatment), 11th day (After Treatment), 26th day (FU1) and 41st day (FU2). Results: For statistical analysis T test was used- was used. Within the group, there was a significant reduction of Intra Ocular Pressure with a p-value <0.0001. Conclusion: There was significant reduction in the values of Intra Ocular Pressure and a nearly normal value was achieved as target Intra Ocular Pressure.

Key Words: Inra-ocular Hydrops, Intra Ocular Pressure, Ocular Hypertension, Ayurveda Protocol, Nasya, Pindi, Bidalaka, Anjana.

Introduction

Shalakyatantra is one among the *Ashtangas* of Ayurveda which deals with disease above the clavicle(1). Intra-ocular Hydrops or Ocular Hypertension is a condition in which there is raised Intra Ocular Pressure above 21mm of Hg without any presenting ocular symptoms(2). Glaucoma refers to visual field defect with glaucomatous optic atrophy and invariably Intra Ocular Pressure(3)

The estimated prevalence of ocular hypertension ranges between 2.7 to 3.8%. Ocular Hyper Tension increases with age, from 1.7 to 2.7% in the age group of 40 to 49 years, 2.7 to 4.6% in the 50 to 59 years range, 4.1 to 7.5% in people older than 80 years(4). It was demonstrated that the rate of untreated Ocular Hyper Tension patients in developing glaucoma was 9.5% in 5 years and 22% at 13 years, or about 2 percent per year. With treatment, the risk of developing glaucoma was reduced by about 50 percent. Thus, Ocular Hyper Tension if not managed effectively may lead to Primary Open Angle Glaucoma which may lead to further complications of glaucoma.

Thus, early diagnosis and effective management of the condition are of prime importance. In contemporary science, the treatment advised for Ocular Hyper Tension is similar to that of Primary Open Angle Glaucoma, i.e. usage of Anti-glaucoma medication in the prescribed dose so that the Intra Ocular Pressure remains controlled(5). The only drawback of anti-glaucoma medications is that they are lifetime medications without much benefit in preventing irreversible visual damage. Studies have stated that there are significant changes in conjunctival structures and tear film as the result of prolonged usage of these medications(6).

Since there is no directly co-relating disease explained in the classics based on the *Dosha* and *Dushya* mimicking disorder *Vataja Adhimantha* is being considered.

Looking into the above facts there is a need for a treatment modality that can effectively reduce the Intra Ocular Pressure and reduce the risk of being affected with Primary Open Angle Glaucoma.

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All classical textbooks have explained various treatment modalities for *Vataja Adhimantha* like *Snaihika Nasya, Virechana, Seka, Anjana, Pindi, Bidalaka, Aschyotana*, etc. Here in this study, a self-developed protocol is being tried which can reduce the Intra Ocular Pressure. The study protocol includes *Nasya*, *Pindi, Bidalaka* and *Anjana*.

For *Nasya, Shatapaki Ksheera Bala Taila* explained in *Ashtanga Hrudaya* has been used in the form of *KBT* 101 drops(7). It contains *Bala Ksheera* and *Tila Taila* which is effective *Vatahara* medicine for *Nasya*. For *Pindi* and *Bidalaka Eranda Pindi – Bidalaka* explained by *Yogaratnakara* in *Netra Roga Chikitsa Prakarana* is taken as *Eranda* is best *Vatahara* as well as *Chakshushya* drug available(8). For *Anjana Gairikadi Anjana Yoga* explained by *Acharya Susrutha* which is prepared out of *Gairika, Saindhava Lavana, Pippali,* and *Shunti* are taken(9). Thus, it is expected that *Vatahara* and *Chakshushya* property of all these drugs may help in the *Samprapti Vighatana*.

During the duration of the study, the patients were assessed based on pre and post-treatment with pre-designed research profiles. The data was collected as pre-treatment (Day 0 – **Before Treatment**), after treatment (Day 11 – **AT**), first follow-up (Day 26 – **FU1**), and second follow-up (Day 41– **FU2).**

Materials and Methods

Study Design

A pilot study was planned with cases of age group 30 to 70 years irrespective of their sex, religion, occupation, etc fulfilling the clinical criteria for diagnosis of Intra-Ocular Hydrops were selected. Cases were taken from the Out Patient Department and In Patient Department section of the KLE Ayurveda Hospital, attached with KAHER's Shri B M K Ayurveda Mahavidyalaya, Shahapur, Belagavi – 590 003.

Ethics compliance

The study was conducted in compliance with applicable ethical guidelines. Institutional Ethics Committee approval on the study protocol, participant information sheet, and informed consent form was obtained before the study initiation. The study was registered with the Clinical Trial Registry of India: CTRI/2020/08/027255 and reviewed by ethical clearance committee with the acceptance letter reference as –BMK/19/PG/SKT/6.

Method of data collection

Subjects diagnosed with Raised Intra Ocular Pressure which are fitting into the inclusion criteria were enrolled in the study and protocol is followed (*Nasya Pindi Bidalaka* and *Anjana*) for 41 days.

Diagnostic criteria

Increased Intra Ocular Pressure noticed during routine investigations.

Inclusion criteria

- Intra Ocular Pressure between 22 to 30 mm of Hg (Asymptomatic cases but noticed raised Intra Ocular Pressure during routine ophthalmic investigations)
- Age group 30 to 70 years
- Irrespective of gender, occupation
- Controlled systemic ailments like DM & HTN
- Known cases of Primary Open Angle Glaucoma with existing standard anti-glaucoma medication with Timolol Maleate 0.5%

Exclusion criteria

- Acute Angle-closure glaucoma
- Intra Ocular Pressure ranging above 30mm of Hg
- Un-controlled systemic disorders like DM, HTN, COut Patient Department, Renal pathologies
- End-stage / advanced glaucomatous optic neuropathy with severe visual morbidity

Intervention

The Protocol of treatment as shown in Table 1.

Assessment criteria

Applanation Tonometry(11)

The ocular tonometry is based on Imbert Fick's principle, where the pressure of an ideal dry, thin-walled sphere is equal to the force required to flatten its surface divided by the flattening area. (P = F / A, where P = pressure, F = force, A = area). In ocular tonometry, the cornea is flattened and intraocular pressure is determined by changing the flattening force or the flattened area._The Goldmann applanation tonometer measures the constrain fundamental to smooth a corneal range of 3.06mm distance across. At this distance across, the resistance of the cornea to straightening is counteracted by the capillary fascination of the tear film meniscus for the tonometer head

Equipment

- Tonometer, either Goldmann (used on slit lamps) or Perkins (hand-held)
- Applanation prism
- Local anesthetic drops
- Fluorescein strips
- Clean cotton wool or gauze swabs.

Preparation

- Make sure the prism is disinfected with 70% isopropyl alcohol (methylated spirits) or 1% sodium hypochlorite. Prism should be rinsed with sterile water and wiped dry with a clean cotton swab (disinfectant residues can cause chemical burns to the cornea).
- Make sure that the scale marked "0" on the measuring prism is aligned with the white mark dot on the tonometer head.
- Make sure the tonometer's calibrated scale is set to 10mmHg
- Make sure the patient is sitting comfortably in the slit lamp. At the correct height, place your chin on the backrest and your forehead on the headband (or on a chair that supports your head if you are using a Perkins tonometer).
- Set the magnification of the slit lamp to × 10.

Table 1- Protocol

Day	Task	Intra Ocular Pressure Evaluation / Assessment
Day 1	Evaluation of Intra Ocular Pressure & Other General conditions	1st Reading Intra Ocular Pressure – BEFORE TREATMENT ICF & CRF Filling (Intra Ocular Pressure was measured every 4th hrly for 24 hrs and mean Intra Ocular Pressure was calculated as BEFORE TREATMENT considering diurnal variation(10)
Day 2	Admission – *KOSHTA SHODHANA with Avipattikara Churna* with Milk	2nd Reading Intra Ocular Pressure Before *Koshtashodhana* 3rd Reading Intra Ocular Pressure After Samyak Koshtashodhana
Day 3 to Day 11	*SNAIHIK NASYA* – 09 Days Morning Hours Before food 8 am *Mukhaabhyanga with Ksheerabala Taila* *Swedana with Bashpa of Ushnajala* *Nasya* with *Ksheerabala* 101 – 14 drops *BIDALAKA* – 09 Days Daily once at 12.30 pm for 30 Minutes Prepared out of fine power of *Eranda Moola* & fresh *Eranda Patra, Eranda Twak* *PINDI* – 09 Days Daily once at 04.00 pm for 30 Minutes Prepared out of fine power of *Eranda Moola* & fresh *Eranda Patra, Eranda Twak* Discharge	4th & 5th Reading Intra Ocular Pressure before & after starting 1st Day (i.e. Day 3) of *Snaihik Nasya, Pindi & Bidalaka* 6th & 7th Reading Intra Ocular Pressure before & after starting 4th Day (i.e. Day 6) of *Snaihik Nasya, Pindi & Bidalaka* 8th & 9th Reading before & after starting 7th Day (i.e. Day 9) of *Snaihik Nasya, Pindi & Bidalaka* 10th & 11th Reading (Before & after treatment value will be recorded and After treatment, value will be considered for AT) before & after completion of *Snaihik Nasya, Pindi & Bidalaka* of 9th Day (i.e. Day 11)
Day 12 to Day 41	*GAIRIKAADI ANJANA* – Fine paste of *Gairika* 1 Part, *Saindhava Lavana* 2 Parts, *Pippali* 4 Parts, and *Nagar* 8 Parts turned into Ointment form and use an ointment. It is to be applied twice daily 8 am and 6 pm. After application one should close both eyes for 15 minutes or till watering subsides. Then wipe the spilled-out medication out of the eye and clean the eyes with cold water swab	12th Reading FU1 Intra Ocular Pressure after 2 weeks of discharge i.e. 26th day after recruitment 13th Reading FU2 Intra Ocular Pressure after 4 weeks of discharge i.e. 41st day after recruitment

Method / SOP of calculating IOP with Goldman

- Instil the local anaesthetic drops and then the fluorescein. Only a very small amount of fluorescein is needed
- For measuring the IOP in the right eye, make sure the slit beam is shining onto the tonometer head from the patient's right side; for the left eye, the beam should come from the patient's left side
- Move the filters so that the blue filter is used to produce a blue beam
- Make sure the beam of light is as wide as possible, and that the light is as bright as possible. This makes visualizing the fluorescein rings easier (with the slit diaphragm fully open)
- Ask the patient to look straight ahead, open both eyes wide, fix his or her gaze and keep perfectly still
- With the thumb, gently hold up the patient's top eyelid, taking care not to put any pressure on the eye
- Direct the blue light from the slit lamp or the Perkins tonometer onto the prism head
- Make sure that the tonometer head is perpendicular to the eye
- Move the tonometer forward slowly until the prism rests gently on the centre of the patient's cornea
- On the other hand, turn the calibrated dial on the tonometer clockwise until the two fluorescein semi-circles in the prism head are seen to meet and form a horizontal 'S' shape. (Note: the correct endpoint is when the inner edges of the two fluorescein semi-circle images just touch)
- Note the reading on the dial and record it in the notes
- Withdraw the prism from the corneal surface and wipe its tip
- Repeat the procedure for the other eye
- Wipe the prism with a clean, dry swab and replace it in the receptacle containing the disinfectant.

Results

T test was used to analyse the results at various stages.

Table no:2 Comparison of before and after treatment effect of *Nasya Pindi Bidalaka & Anjana* over Intra Ocular Pressure in right and left eye

	Treatment	Mean	SD	Mean	SD Diff.	% of change	t-value	p-value
Intra ocular Pressure in right eye	**Before Treatment**	25.26	1.64					
	During treatment 1	23.30	1.77	1.96	1.31	7.75	4.7146	0.0011*
	Before Treatment	25.26	1.64					
	During treatment 2	22.70	1.57	2.56	0.87	10.12	9.3138	0.0001*
	Before Treatment	25.26	1.64					
	After treatment	22.30	1.89	2.96	1.32	11.71	7.0782	0.0001*
	During treatment 1	23.30	1.77					
	During treatment 2	22.70	1.57	0.60	0.84	2.58	2.2500	0.0510
	During treatment 1	23.30	1.77					
	After treatment	22.30	1.89	1.00	1.70	4.29	1.8605	0.0957
	During treatment 2	22.70	1.57					
	After treatment	22.30	1.89	0.40	1.35	1.76	0.9370	0.3732
	Before	25.26	1.64					
	Follow Up 1	22.50	2.07	2.76	1.38	10.92	6.3333	0.0001*
	Before	25.26	1.64					
	Follow up 2	22.40	1.96	2.86	1.28	11.31	7.0402	0.0001*
	Follow Up 1	22.50	2.07					
	Follow Up 2	22.40	1.96	0.10	0.99	0.44	0.3180	0.7577
Intra Ocular Pressure In left eye	**Before Treatment**	24.85	1.59					
	During treatment 1	23.40	1.71	1.45	0.77	5.84	5.9284	0.0002*
	Before Treatment	24.85	1.59					
	During treatment 2	23.20	1.87	1.65	0.95	6.65	5.4895	0.0004*
	Before Treatment	24.85	1.59					
	After treatment	22.70	1.89	2.15	1.00	8.66	6.8316	0.0001*
	During treatment 1	23.40	1.71					
	During treatment 2	23.20	1.87	0.20	0.92	0.85	0.6882	0.5086
	During treatment 1	23.40	1.71					
	After treatment	22.70	1.89	0.70	1.25	2.99	1.7685	0.1108
	During treatment 2	23.20	1.87					
	After treatment	22.70	1.89	0.50	0.53	2.16	3.0000	0.0150*
	Before	24.85	1.59					
	Follow Up 1	22.10	1.97	2.75	1.07	11.07	8.1401	0.0001*
	Before	24.85	1.59					
	Follow up 2	22.60	1.90	2.25	0.75	9.06	9.5101	0.0001*
	Follow Up 1	22.10	1.97					
	Follow Up 2	22.60	1.90	-0.50	0.53	-2.26	-3.000	0.0150*

*p<0.05

Table shows the effect of *Nasya Pindi and Bidalaka* at various time points During Treatment1, During Treatment2 and AT. The mean IOP Before Treatment was 25.26 in right eye and 24.85 in left eye which was reduced by 7.75% in right eye and 5.84% in left eye during During Treatment1(3 days after *Nasya Pindi and Bidalaka),* 10,12% in right eye and 6.65% in left eye during During Treatment2 (6 days after *Nasya Pindi and Bidalaka),* 11.71% in right eye and 8.66% in left eye during AT(9 days after *Nasya Pindi and Bidalaka),* Thus there was a change of mean value from 25.26 to 22.30 in right eye (t value 7.0782 & p value 0.0001)and 24.85 to 22.70 in left eye (t value 6.8316 & P value 0.0001) after 9 days of *Nasya Pindi and Bidalaka* which shows statistically significant change of IOP values at significance level p value < 0.05. The mean IOP BT was 25.26 in right eye and 24.85 in left eye which was reduced by 10.92% on FU1 in right eye and 11.07% in left eye (i.e 15th day of application of *Anjana*) and reduced by 11.31% in right eye and 9.06% in left eye on FU2 (i.e 30th day after application of *Anjana*). Thus there was a change of mean value from 25.26 to 22.40 in right eye and 24.85 to 22.60 in left eye (t value -3.000& P value 0.0150) after 30 days of *Anjana* which shows statistically significant change of IOP values at significance level p value < 0.05

Discussion

Probable Mode of Action of *Avipattikara Choorna*

This was being used as a pre-requisite for conducting *Kriyakalpa* & *Panchakarma* procedures. Ingredients of *Avipattikara* have multiple actions like *Deepana*, *Paachana*, *Anulomana*, *Koshta Shodhana*, *Agni Samvardhana*, *Prasadana*, *Vaatanulomana*, *Aamapaachana,* etc. which helps in *Doshavilayana* and *Srothovisodhana*. *Anulomana* action cleanses the *Sanchit* Mala and vitiated *Vaata* at its *Sthaana* i.e. *Pakwashaya*, thus might control, the action of vitiated *Vaata* elsewhere in the body(12). *Avipattikara* drug has nectareous action over vitiated *Pitta* and *Rakta*, thus might controls over the derangement of *Sthaanika Dosha* in *Netra* Ii.e. *Alochaka Pitta*. Fluid loss during *Koshta Shodhana* action might contribute to reducing Intra Ocular Pressure momentarily**,** just like the action of systemic action by Acetazolamide, Mannitol, etc(13).

Probable Mode of Action of *Ksheerabala Taila* 101

Snigdha Guna and *Madhura Vipaka* being *Vatahara* might help in reliving the *Sanga* and *Rookshatha* in *Netra Vahi Siras* (14). Thus it might help in relieving ciliary spasms and reduce the Intra Ocular Pressure by improving the secretion and drainage of the aqueous. Thus Prevents further damage to Anatomical structures (i.e. flexibility & lumen of ciliary vessels / aqueous draining system – Schlemm's canal and Trabecular Meshwork). KBT reduces oxidative stress thus might help in reducing Intra Ocular Pressure as oxidative stress can also be considered as an etiology for raised Intra Ocular Pressure(15).

KBT has proven neuroprotective action using controlling oxidative stress which might also contribute to the action (16). The presence of Flavanoids and Glycosides in Bala exert anxiolytic & sedative effects on the central nervous system which also might contribute to the reduction of Intra Ocular Pressure(17).

Thus altogether *Nasya* with *KBT 101* might help to reduce Intra Ocular Pressure and prevent the progression of the disease –into Primary Open Angle Glaucoma.

Probable mode of action of *Eranda*

Eranda is praised as the best *Vatahara* and *Chakshushya* drug. *Eranda* has *Madhura Rasa, Madhura Vipaka* and *Snigdha Guna* which act as *Vata Shamaka.* All these properties might help in reliving the *Sanga* and *Rookshata* in the *NertaVahi Siras* thus might facilitate the easy drainage of the aqueous thus helping in *Samprapti Vighatana* (18). Ricinus was used to treat eye disorders in various traditional systems of medicines practiced (19). The lipophilic nature of Ricinolein in *Eranda* helps in the easy absorption of active principles through the skin and ocular surface which facilitates the quick absorption of active principles thus, in turn, help in reducing the Intra Ocular Pressure (20). The Ricinoleic acid in Ricinus has proven anti-inflammatory action which reduces the active inflammation present in the ciliary vessels and might relieve ciliary spasm thus reducing Intra Ocular Pressure(21).

Probable mode of action of *Gairikadi Anjanaa*

Gairikadi Anjana falls under the category of *Teekshna Lekhana Anjana*. Being Teekshna it can be stimulatory in action and thus might stimulate the secretion and quick drainage of aqueous. *Gairikadi Anjana* being a *Teekshna Anjana* might be *Sroto-Shodhaka* and *Vatahara* as the ingredients are also *Vatahara*. Since *Srotho Sodhana* and *Vata Harana* is the prime goal of the *Chikitsa Gairikadi* Anjana might help in the *Samprapti Vighatana,* This might reduce Intra Ocular Pressure.

Gairika

Having *Snigdha*, *Sheeta Guna*, *Sheeta Virya, Chakshushya* and is *Vatahara* in nature. This might help in reliving the *Rookshata* of the *Netra Vahi Siras* and also might help in balancing the *Ushnatva* of the *Anjana* by its *Sheeta Veerya*. Since it is *Chakshushya* in nature add on effect on vision and improving general eye health might be expected

Pippali

Pippali has *Madhura Anurasa, Laghu Snighdha, Teekshna Guna*, *Anushna Sheeta Veerya* and *Madhura Vipaka* act as *Vatahara*, the *Teekshna Guna* helps in reliving the *Sangha* in the *Netra Vahi Siras.* The *Snigdha* and *Laghu Guna* help in reliving the *Rookshata* in the *Siras* which in turn helps in reducing Intra Ocular Pressure. Piperine in *Pippali* has proven antioxidant action which helps in relieving oxidative stress which is also considered a reason for raised Intra Ocular Pressure(22).

Shunti

Shunti having *Katu Rasa*, *Laghu Snigdha Guna, Madhura Vipaka*, and *Vata – Kapha hara* action helps in relieving the *Sangha* in the *Netravahi Siras* and *Snigdha Guna* helps in reliving the *Rookshata* of the *Siras*. The *Vata Kaphahara* property also tackles the *Sthanika Dosha* vitiated and thus might help in the *Samprapti Vighatana.* The prostaglandin inhibition property of zingiberene plays a vital role in the reduction of Intra Ocular Pressure as prostaglandins are the elements that raise the Intra Ocular Pressure(23). Thus, the prostaglandin inhibition property indirectly helps in the reduction of Intra Ocular Pressure**.** Leukotrienes are considered the neuroinflammatory mediators involved in the pathogenesis of neurodegenerative diseases. Thus the leukotriene synthesis property of Zingiber in *Shunti* might help in preventing the neuroglial cell death and thus preventing further atrophic damage to optic nerve.

Anti-oxidant Nature of Vitamin C in *Shunti* helps in releasing oxidative stress and thereby might contribute to reducing Intra Ocular Pressure**.** Platelet-activating factors are groups of proteins that actively take part in the inflammatory process of ocular tissues like iris ciliary bodies etc. Inflammatory changes in ciliary bodies create ciliary spasms which increase the Intra Ocular Pressure. Zingiberene relives ciliary spasms by its ability to thin out platelet aggregation in the ciliary body thus helping in reducing Intra Ocular Pressure(24).

Saindhava Lavana

Saindhava Lavana has *Madhura Rasa*, *Laghu Snigdha*, *Ushna Guna*, *Madhura Vipaka,* and *Chakshushya. Saindhava* is also considered as *Vata – Kapha hara* thus might help in relieving the *Sanga* and *Rookshatha* in the *Netravahi Siras* which might help in reducing Intra Ocular Pressure. *Saindhava is* also said to possess *Vyavayi* and *Vikashi Guna* which might help in the accelerated action of the formulation(25).

Conclusion

The *Ayurvedic* Protocol (*Nasya*, *Pindi*, *Bidalaka*, and *Anjana*) was effective in reducing the Intra Ocular Pressure but was not able to reduce the Intra Ocular Pressure to the normal range.

Informed consent statement

Written informed consent was obtained from all subjects involved in the study for their participation and publication of data without revealing their identity.

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Conflicts of interest

The authors have no conflicts of interest to declare that are relevant to the content of this article.

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