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An Open Label Double Arm Controlled Clinical Study on the Efficacy of Vibhitakadi Eye Ointment in Shushkakshipaka (Digital Eye Strain)

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ABSTRACT

Background: Digital Eye Strain (DES) refers to a group of eye and vision problems caused by prolonged use of Visual Display Terminals (VDT) such as computers, tablets, and smartphones. Common symptoms include dryness of eyes, foreign body sensation, photophobia, itching, watering, redness, burning sensation, blurred vision, gritty feeling, and heaviness of eyelids. The worldwide prevalence of dry eye disease is approximately 11.59%, and about 70% of cases are associated with prolonged digital screen use. In Ayurveda, Shushkakshipaka is described as one of the Sarvagata Netra Rogas, mainly caused by the vitiation of Vata and Pitta doshas, and its clinical features closely resemble those of DES. Conventional treatments for dry eye include artificial tear substitutes in the form of drops, gels, and ointments. However, these require frequent instillation due to their short duration of action and may cause sensitivity because of preservatives present in the formulations.

Methodology: Open label double arm controlled Interventional clinical study was conducted on 40 subjects diagnosed as Shushkakshipaka (Digital Eye Strain) was randomly assigned into two groups i.e., Group A(Control Group) and Group B(Trial Group) , each comprising 20 patients. Group A was treated with Vibhitakadi Ghrita and Group B with Vibhitakadi Eye Ointment for a period of 30 days. Patients were assessed before treatment after treatment and during follow-up (0, 30th, 45th day). The assessment was carried out based on subjective parameters such as Ruksha (Dryness of eyes), Gharsha (Foreign body sensation), Daha (Burning Sensation), Prakasha asahishnuta (Photophobia), Toda (pricking pain), Daruna vartma (painful and discomfort lids), Krichronmeelana (difficulty in opening and closing of eye lids), Avila Darsana (Transient Blurring of vision) along with objective evaluation such as Schimer's test, Tear film break-up time, Tear meniscus height, OSDI grading. The collected data were analyzed using appropriate statistical methods to evaluate the therapeutic efficacy of the intervention.

Result: The study showed significant improvement in both subjective and objective parameters, including OSDI grading, indicating good prognosis. Both Vibhitakadi Ghrita Aschyotana and Vibhitakadi Eye Ointment were effective in managing Shushkakshipaka (Digital Eye Strain). Group B (eye ointment)

demonstrated better results in symptoms like Avila Darshana, Ruksha, Prakasha Asahishnuta, Toda, Krichronmeelana, and tear film parameters. Although no significant difference was found statistically between groups, intra-group analysis suggested greater effectiveness of Group B, likely due to prolonged contact time and the added effect of Madhuchista

Conclusion: Vibhitakadi Eye Ointment is a promising, patient-friendly, and easy-to-use intervention that may effectively reduce the symptoms of Shushkakshipaka (Digital Eye Strain) and improve the quality of life on affected patients. It may be considered as a safe, convenient and effective therapeutic option in the management of Shushkakshipaka

Keywords: Vibhitakadi Eye Ointment, Shushkakshipaka, Digital Eye Strain, Dry Eye

INTRODUCTION

Shushkakshipaka is a Sadhya Vyadhi under Sarvagata Netra Rogas, caused by vitiation of Vata and Pitta. Its clinical features such as Gharsha, Toda, Bheda, Upadeha, Krichronmeelana and Ruksha-Daruna Vartma closely resemble the symptoms of Digital Eye Strain, including irritation, fluctuating blurred vision, and photophobia. Digital Eye Strain significantly affects quality of life and may lead to serious complications if untreated.

Modern treatments like tear substitutes provide only short-term symptomatic relief, highlighting the need for safer, economical, and more effective therapies. Ayurveda recommends Snehapana, Nasya, Aschyotana, Anjana, and other Vatahara measures. Vibhitakadi Ghrita, mentioned in Yogaratnakara, is indicated for Shushkakshipaka due to its Vata-Pittahara, Chakshushya, and Ropana properties.

Since drug retention in Aschyotana is limited, the Ghrita was modified into an ointment form using bee wax (1:6 ratio) to enhance ocular retention, improve bioavailability, and increase patient compliance. Thus, Vibhitakadi eye ointment is proposed as a novel, patient-friendly, and effective therapeutic option for managing Shushkakshipaka (Digital Eye Strain).

MATERIAL AND METHOD

Subjects

Participants falling under diagnostic and inclusion criteria were recruited approaching the Outpatient and Inpatient department of Shalakya Tantra, Shri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital, Bengaluru. Inclusion criteria for the study were: 1. Patients presented with lakshanas of Shushkakshipaka. 2. Patients with Evaporative type of dry eye with intrinsic factors. 3. Patients who were using digital screens for more than 3 hours daily in a stretch. 4. Patients aged between 25 to 50 years. 5. Patients of either sex. Exclusion criteria were: 1. Patients suffering from systemic, metabolic disorders that has caused Dry eyes 2. Patients with Aqueous deficient Dry Eye (Sjogren Syndrome, Menopausal women, Lacrimal gland dysfunction) 3. Patients under the medications that causes dry eyes (antihistamines decongestants, hormonal therapy, antidepressants, dermatologic medications, antipsychotic medications, and chemotherapy medications.) 4. Congenital anomalies of eye.

Intervention

Group A- Control group- Vibhitakadi Ghrita Aschyotana

Sample Size: 20	
Vibhitakadi Ghrita Aschyotana	Aschyotana (Snehana type) was advised once a day with dosage of 10 drops for each eye in evening time.
Duration of Treatment	30 days
Assessment	• Before Treatment (Day 0) • After Treatment (Day 30) • Follow-up (Day 45)

Group B- Trial Group – Vibhitakadi eye Ointment

Sample Size: 20	
Vibhitakadi Eye Ointment	Application of Eye Ointment was advised Once a day at night time
Duration of Treatment	30 days
Assessment	• Before Treatment (Day 0) • After Treatment (Day 30) • Follow-up (Day 45)

Ingredients of Vibhitakadi Ghrita

Sl	Sanskrit name	Botanical name	Part used	Proportion
1.	Go ghrita	Cow's ghee	-	1 kg
2.	Water	Water	-	16 L
3.	Vibhitaki	Terminalia bellirica Roxb	Fruit	250g
4.	Haritaki	Terminalia chebula Retz	Fruit	250g
5..	Amalaki	Emblica officinalis Gaertn	Fruit	250g
6.	Nimba	Azadirachta indica Linn	Leaves	250g
7.	Patola	Trichosanthes dioica Roxb	Leaves	250g
8.	Vasa	Adhatoda vasica Nees	Leaves	250g

Ingredients of Vibhitakadi Eye Ointment

Sl	Sanskrit name	Proportion
1	Vibhitakadi ghrita	600g

2	Maduchishta	100g

Assessment Schedule

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

ASSESSMENT CRITERIA- GRADATION INDEX

Sl	Lakshana	Grade- 0	Grade- 1	Grade- 2	Grade- 3
1	**Avila Darshana**	Absent	Occasionally present	Intermittently present	Frequently present
2	**Ruksha**	No feeling of dryness	Occasional/ episodic, occurs under environmental stress	Frequent/ episodic, with or without environmental stress	Constant without environmental stress
3	**Gharsha**	Absent	Occasionally present	Frequently present with lacrimation	Continuously present with lacrimation and congestion
4	**Daha**	Absent	Occasional burning sensation in eyes and tolerable	Frequent burning sensation in eyes and relives on rest	Continuous burning sensation does not relive on any measures
5	**Prakasa asahishnuta**	Absent	Sensitivity to bright sun light and other bright stimulus	Sensitivity to mild sunlight but comfortable in dim lights	Sensitivity to even dim light with inability to open eye
6	**Toda**	Absence of pricking pain	Tolerable, negligible	Constant, tolerable	Constant. Intolerable
7	**Daruna vartma**	Absent	Occasionally present	Frequently Present	Continuously Present throughout the day
8	**Krichronmeelana**	Absence of symptoms	Occasionally felt and negligible, under environmental stress	Frequently felt and negligible, with or without environmental stress	Constantly felt without environmental stress

9	**Schirmer's test**	Level of wetting of tear strip above 15mm in 1 minute.	Level of wetting of tear strip above 10mm - 15mm in 1 minute	Level of wetting of tear strip above 5mm - 10mm in 1 minute	Level of wetting of tear strip at 1mm - 5mm in 1 minute
10	**Tear Film break up time**	The appearance of dry spots after 15 sec	The appearance of dry spot between 10-15 sec	The appearance of dry spot between 5-10 sec	The appearance of dry spot with in 5 sec
11	**Tear meniscus height**	TMH 1/2 lid margin thickness	TMH 1/3 lid margin thickness	TMH 1/4 lid margin thickness	TMH 1/6 lid margin thickness

OBSERVATION

Demographic Data

Sl.no	Demographic Data	Percentage
1	Age	25- 30- 35% 36-40- 22.5%
2	Gender	Male – 62.5% Female – 37.5%
3	Religion	Hindu – 100%
4	Family History	92.5% subjects had a negative family history
5	Occupation	IT profession – 50 % Office work – 20 %
6	Screen Time	9-10 hours- 55% 7-8 hours- 35%
7	Prakruti	Vata-pitta- 55% Vata-kapha- 42.5%
8	Nidana	Sookshmanireekshana- 77.5% Ruksha Ahara- 65%
9	Lakshana	Ruksha- 100% Avila Darshana- 92.5 % Daha- 85%

Lakshanas

Lakshanas	Group A		Group B		Total	%
	Frequency	%	Frequency	%		
Avila Darsana	19	95	18	90	37	92.5
Ruksha	20	100	20	100	40	100
Gharsha	12	60	12	60	24	60
Daha	17	85	17	85	34	85

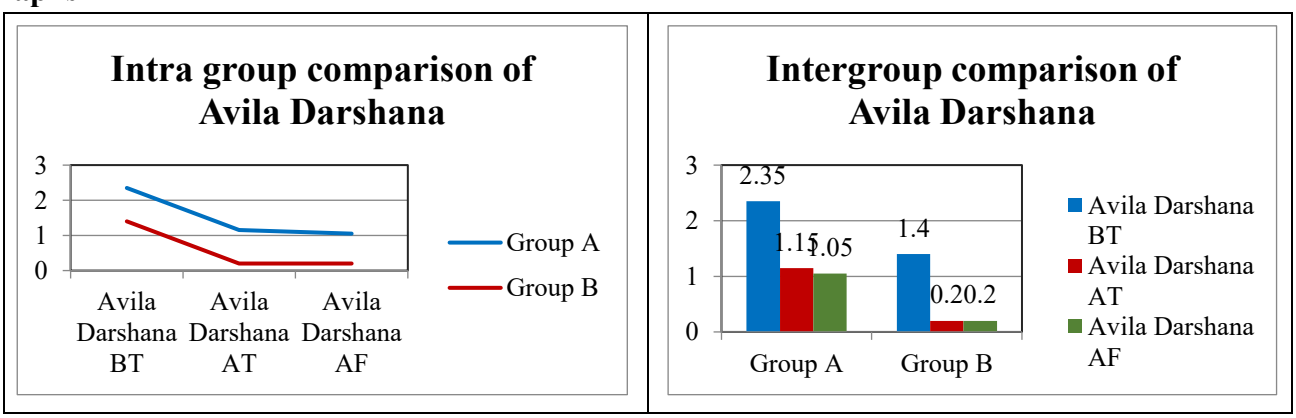
Prakasa Asahishnuta	15	75	16	80	31	77.5
Toda	14	70	11	55	25	62.5
Daruna Vartma	5	25	5	25	10	25
Krichronmeelana	5	25	3	15	8	20

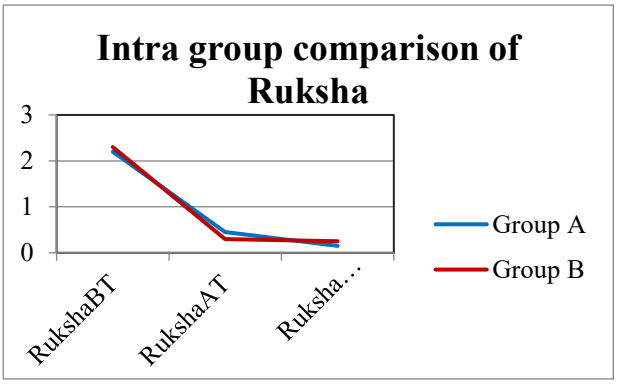
Though the patients enrolled for the present study had all the classical symptoms of Shushkakshipaka, 100% of the patients had Ruksha Netra and only few patients presented with Daruna vartma and Krichronmeelana which shows the prevalence of these lakshanas in this present study.

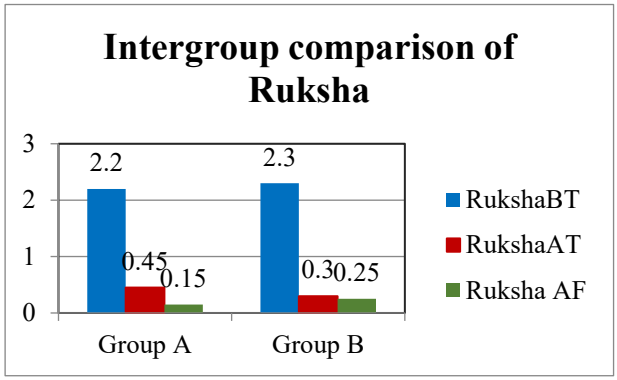
RESULTS.

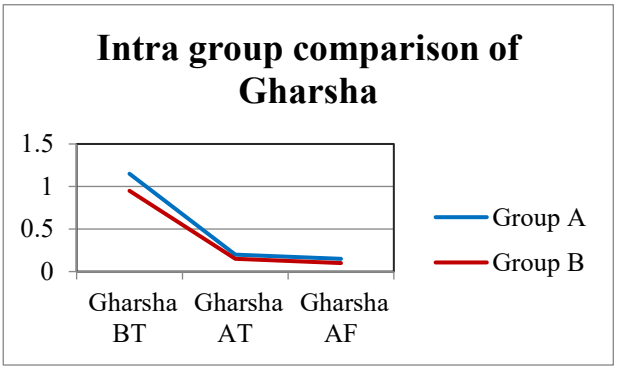
Sl. No	Lakshanas	χ^2 Values of Intra Group A	χ^2 Values of Intra Group B	Between the group
1	Avila Darsana	26.909	34.000	Statistically Non Significant, But χ2 Values of Group B showed Better results
2	Ruksha	34.656	39.377	
3	Gharsha	27.395	27.395	Statistically Non Significant, χ2 values also showed equal effects.
4	Daha	34.000	33.385	
5	Prakasa Asahishnuta	25.400	32.000	Statistically Non Significant, But χ^2 Values of Group B showed Better results
6	Toda	28.000	21.412	Statistically Non Significant, But χ^2 Values of Group A showed Better results
7	Daruna Vartma	10.000	10.000	Statistically Non Significant, χ2 values also showed equal effects.
8	Krichronmeelana	8.000	6.000	Statistically Non Significant, But χ^2 Values of Group A showed Better results
9	Schirmers test	34.105	38.381	Statistically Non Significant, But χ^2 Values of Group B showed Better results
10	TBUT	35.382	40.000	
11	Tear meniscus height	36.000	35.621	Statistically Non Significant, χ2 values also showed equal effects.
12	OSDI grading	40.000	40.000	

Graphs




Intra group comparison of Ruksha
3
2
1
0
RukshaBT
RukshaAT
Ruksha…
Group A
Group B


Intergroup comparison of Ruksha
3
2
1
0
2.2
0.45
0.15
2.3
0.3
0.25
Group A
Group B
RukshaBT
RukshaAT
Ruksha AF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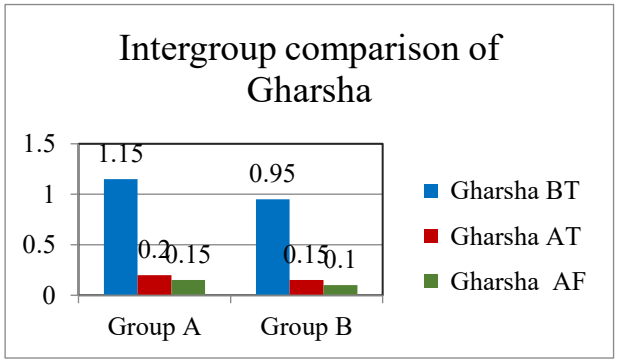
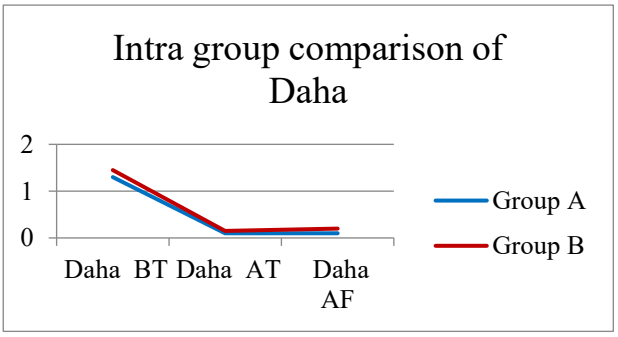
1.5
1
0.5
0
Gharsha BT
Gharsha AT
Gharsha AF
Group A
Group B


Intergroup comparison of Gharsha
1.5
1
0.5
0
1.15
0.2
0.15
0.95
0.15
0.1
Group A
Group B
Gharsha BT
Gharsha AT
Gharsha AF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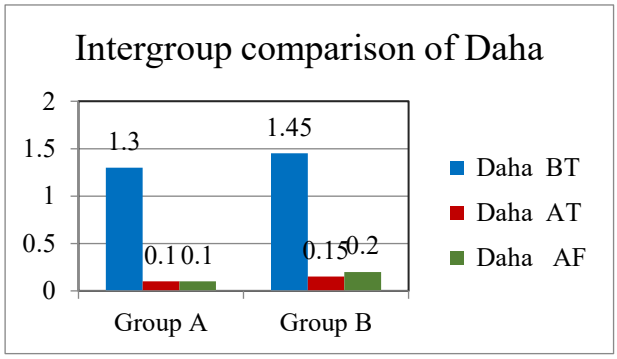
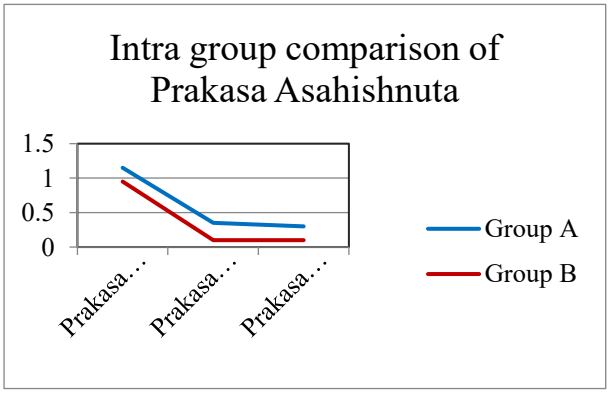
2
1
0
Daha BT
Daha AT
Daha AF
Group A
Group B


Intergroup comparison of Daha
2
1.5
1
0.5
0
1.3
0.1
0.1
1.45
0.15
0.2
Group A
Group B
Daha BT
Daha AT
Daha AF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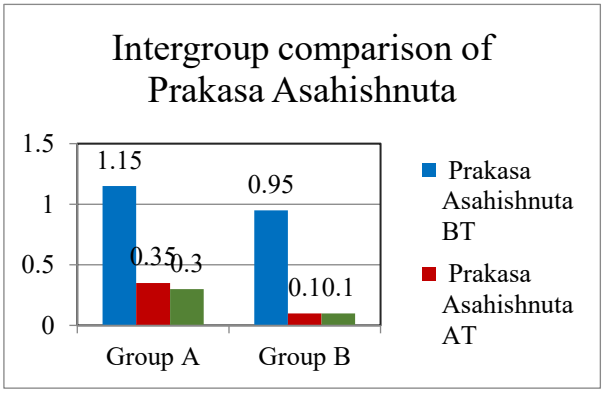
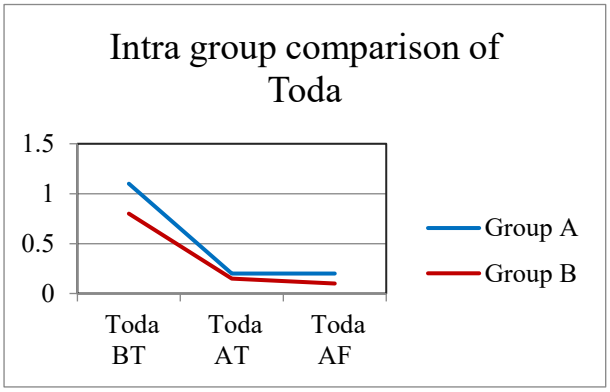
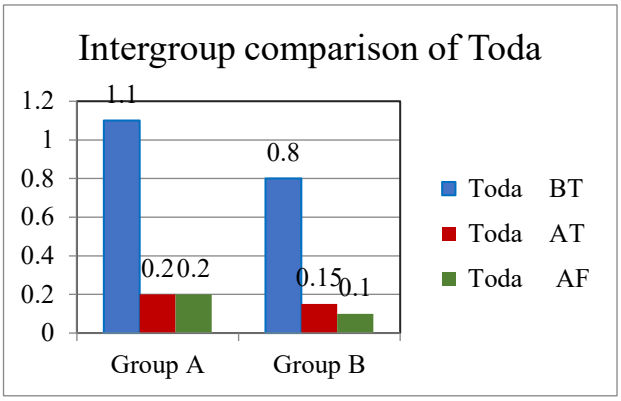
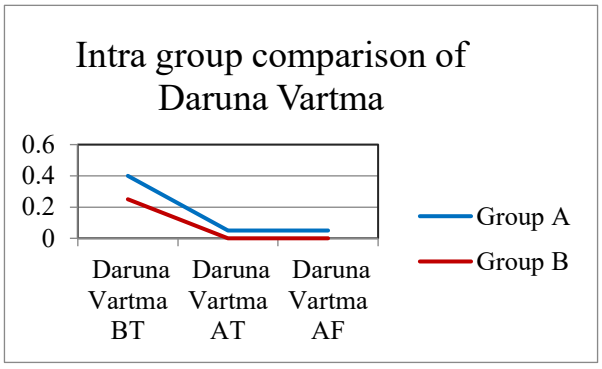
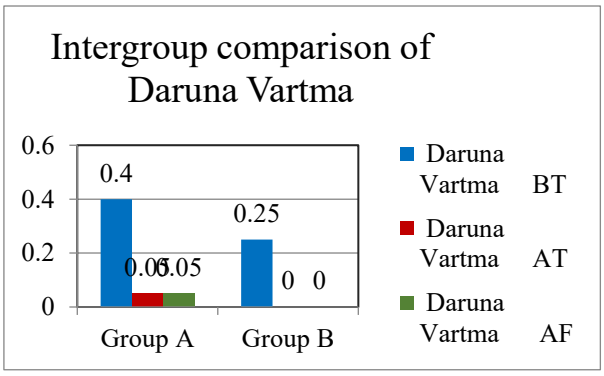
1.5
1
0.5
0
Prakasa…
Prakasa…
Prakasa…
Group A
Group B

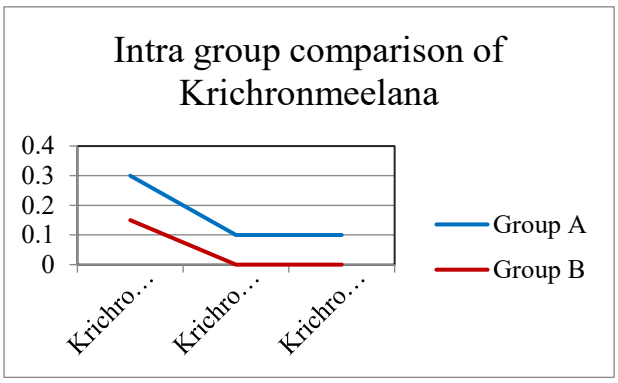

Intergroup comparison of Prakasa Asahishnuta
1.5
1
0.5
0
1.15
0.35
0.3
0.95
0.1
0.1
Group A
Group B
Prakasa Asahishnuta BT
Prakasa Asahishnuta AT

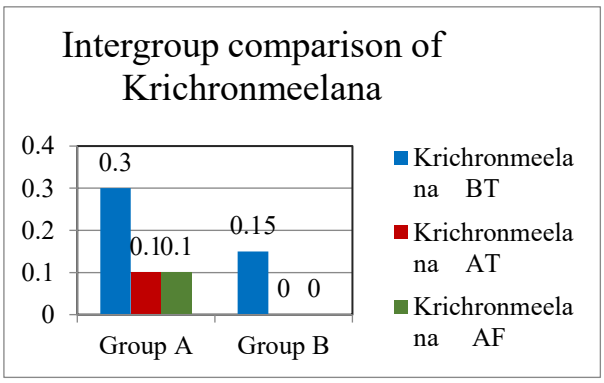

Intra group comparison of Toda
1.5
1
0.5
0
Toda BT
Toda AT
Toda AF
Group A
Group B

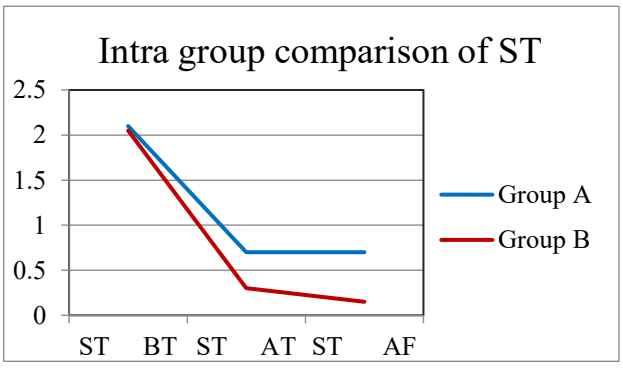

Intergroup comparison of Toda
1.2
1
0.8
0.6
0.4
0.2
0
1.1
0.2
0.2
0.8
0.15
0.1
Group A
Group B
Toda BT
Toda AT
Toda AF

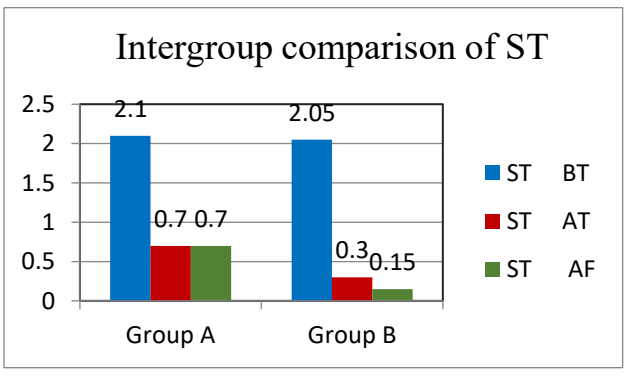

Intra group comparison of Daruna Vartma
0.6
0.4
0.2
0
Daruna Vartma BT
Daruna Vartma AT
Daruna Vartma AF
Group A
Group B

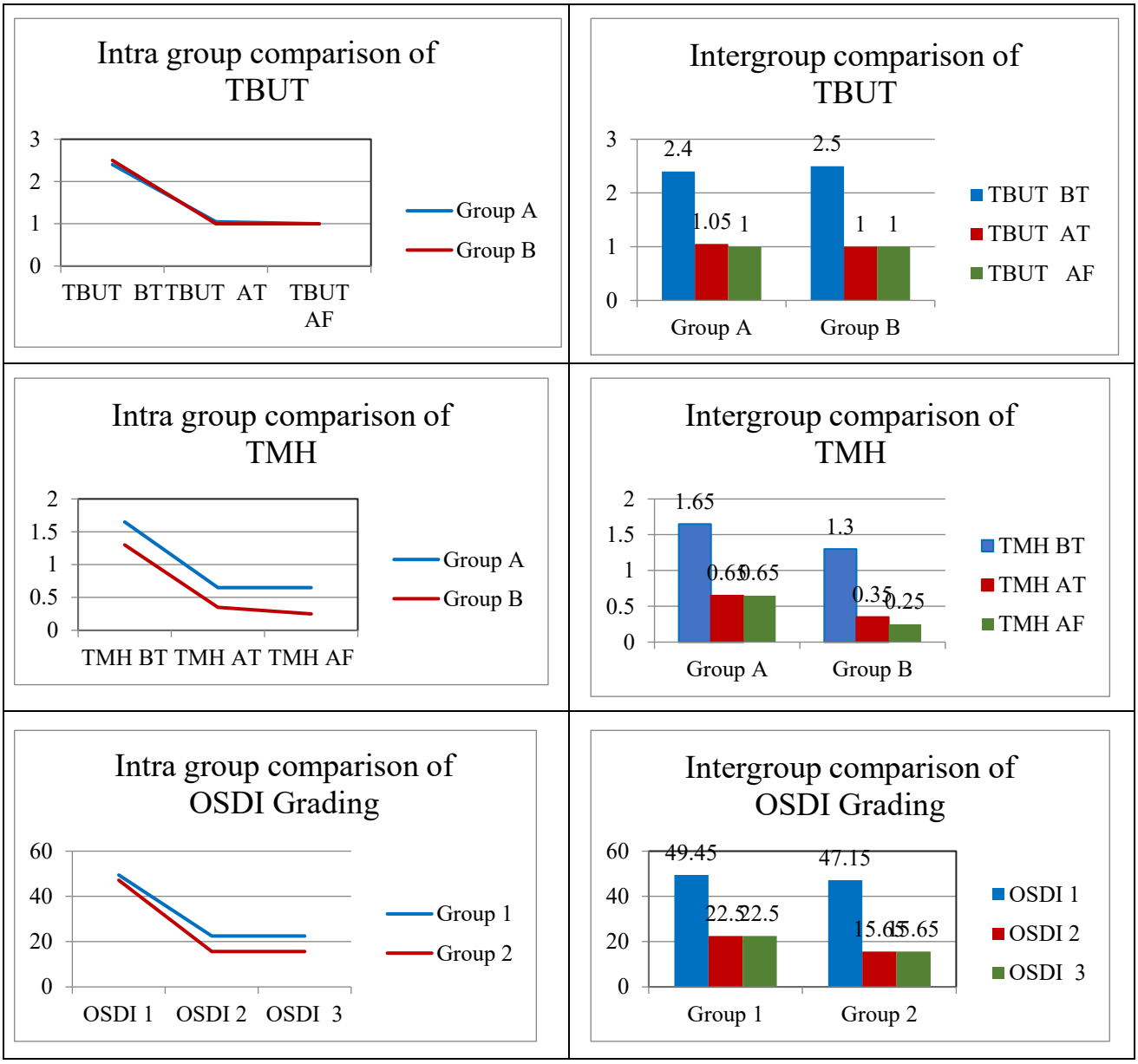

Intergroup comparison of Daruna Vartma
0.6
0.4
0.2
0
0.4
0.05
0.25
0 0
Group A
Group B
Daruna Vartma BT
Daruna Vartma AT
Daruna Vartma AF


Intra group comparison of Krichronmeelana
0.4
0.3
0.2
0.1
0
Krichro…
Krichro…
Krichro…
Group A
Group B


Intergroup comparison of Krichronmeelana
0.4
0.3
0.2
0.1
0
0.3
0.1
0.1
0.15
0 0
Group A
Group B
Krichronmeelana BT
Krichronmeelana AT
Krichronmeelana AF


Intra group comparison of ST
2.5
2
1.5
1
0.5
0
ST BT ST AT ST AF
Group A
Group B


Intergroup comparison of ST
2.5
2
1.5
1
0.5
0
2.1
0.7
0.7
2.05
0.3
0.15
Group A
Group B
ST BT
ST AT
ST AF



DISCUSSION

Selection of Problem

Digital Eye Strain (DES) has been selected for this study due to its rising prevalence in modern lifestyles, where prolonged use of digital devices for work, education, and recreation has become unavoidable. It is characterized by symptoms such as dryness, foreign body sensation, photophobia, itching, redness, burning, blurred vision, and heaviness of eyelids, significantly affecting quality of life and work productivity.

The global prevalence of dry eye disease is around 11.59%, with nearly 70% of cases linked to excessive screen use. Current treatments like artificial tears offer only temporary relief, require frequent use, and may cause sensitivity. Therefore, there is a need for safe, effective, and long-lasting alternatives, as untreated DES can progress to serious ocular complications

Selection Of Drug

Among the various formulations indicated for Shushkakshipaka, Vibhitakadi Ghrita described in Yogara-

atnakara was selected for this study based on its relevance to both Ayurvedic and modern pathophysiology. The condition involves vitiation of Vata–Pitta dosha and Tejojalashrita patala, and the formulation—containing Amalaki, Haritaki, Vibhitaki, Vasa, Nimba, Patola, and Go-ghrita—possesses Kashaya-Tikta rasa, Sheeta virya, Madhura vipaka, and Laghu-Snigdha guna, making it Tridosha-shamaka with Chakshushya, Snehana, Rasayana, and Dahaprashamana properties.

From a modern perspective, its constituents exhibit antioxidant, anti-inflammatory, demulcent, analgesic, glandular stimulant, and epithelio-protective actions. Additionally, the formulation is free from preservative-related toxicity, economical, easily available, associated with minimal side effects, and convenient for administration.

Procedure

Aschyotana (instillation of medicated drops) is considered the first-line therapy in ocular disorders, indicated in symptoms like pain, itching, burning, redness, watering, and irritation. The drug is absorbed through the tear film layers—lipid, aqueous, and mucous—allowing penetration into deeper ocular structures. In this study, Vibhitakadi Ghrita Aschyotana was administered as 10 drops in the evening for Snehana. Eye ointments act mainly by providing prolonged contact of the drug with the ocular surface. Their semisolid, greasy base allows the medication to remain in the conjunctival sac longer than eye drops, thereby increasing absorption and effectiveness. Once applied, the ointment spreads over the tear film, forming a thin layer that gradually releases the drug. This enhances penetration into the cornea, conjunctiva, and, in some cases, the anterior chamber. In addition to drug delivery, the ointment base itself provides a lubricating effect, and there by reducing friction between the eyelids and the ocular surface. However, due to their oily consistency, ointments may temporarily blur vision so time of administration of eye ointment is usually bedtime. Here in this study, Vibhitakadi Ghrita was converted to Vibhitakadi eye ointment with Bee wax (1 part of Bee wax to 6 parts of Vibhitakadi Ghrita) as base.

Mode of Action

The trial drug, Vibhitakadi Eye Ointment is Vata-Pitta shamaka by virtue of its Rasa, Guna, Virya and Prabhava. In Shushkakshipaka there is increase in Vata Pitta Doshas which is decreased by the Snigdha Guna and Madhura Rasa of Vibhitakadi Eye Ointment. It will also help in reducing the Rukshata of Vata Dosha, increase Dravata of Pitta Dosha and also increases Jalamahabhuta. thereby addressing the underlying pathogenesis of Shushkakshipaka, which is primarily of Vata-Pitta origin.

As per analytical study the pH of Vibhitakadi eye ointment is 7 makes it close to the normal pH of human tears (6.5–7.6), which ensures good compatibility with the tear film and avoids irritation such as burning or stinging. This neutrality provides better comfort for sensitive dry eye patients, allows the ointment to remain longer on the ocular surface, and enhances lubrication by forming a stable protective film. It also supports the stability and absorption of the active ingredients while maintaining ocular surface homeostasis, thereby helping in the effective management of Shushkakshipaka.

The spreadability of Vibhitakadi eye ointment is 11.89 it can form a thin, uniform film over the ocular surface, ensuring better lubrication, reduced friction, and improved comfort in dry eye.

A refractive index of 1.4, which is close to that of the natural tear film, helps Vibhitakadi eye ointment maintain optical clarity while coating the ocular surface. This reduces visual disturbances like blurring, ensures smooth light transmission, and at the same time provides a protective lubricating layer, thereby relieving dryness and discomfort in dry eye.

Vibhitakadi eye ointment was subjected to analytical study for standardization, and the results indicated that its parameters were comparable to those of the control group, which has already been proven effective in the management of Shushkakshipaka. This establishes the reliability and quality of the formulation while supporting its therapeutic potential in addressing Shushkakshipaka.

Discussion on Results

According to current study, all the parameters both subjective and objective along with OSDI grading showed good prognosis. Clinically Shushkakshipaka (Digital Eye Strain) is a Vata-Pitta predominant disease. Both Vibhitakadi Ghrita Aschyotana and Vibhitakadi Eye Ointment demonstrated clinical improvement in the management of Shushkakshipaka (Digital Eye Strain). However, specific parameters showed differences in effectiveness between the two procedures. Group B showed more effective in parameters like Avila Darshana, Ruksha, Prakasha Asahishnuta, Toda, Krichronmeelana, Schirmers test , TBUT, Tear meniscus height. Though in the statistical analysis, no significant difference was observed between the trial and control groups. However, intra-group comparison on Chi-Square values revealed that Group B demonstrated greater effectiveness, which may be attributed to the additional effect of Madhuchista and the prolonged contact time of the eye ointment, providing consistent relief in the assessed parameters.

Scope for Future Study

Current study along with preventive measures and Eye exercises need to be explored. Research on the mechanism of action of Vibhitakadi Eye ointment at the level of tear film dynamics and ocular surface health will provide deeper insights. Multicentric clinical trials can enhance generalizability of results across different demographic and environmental conditions. Exploring its preventive potential in early stages of Digital Eye Strain before the onset of severe symptoms. Other Ayurvedic formulations can also be converted into eye ointment form and their efficacy in managing digital eye strain may be further explored.

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