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A large, stylized DNA double helix structure is the central focus of the cover. It is rendered in shades of blue and purple, with colorful spheres representing the base pairs. In the center of the helix, there is a small potted plant with green leaves and purple flowers, and several wooden gongs or bangles are scattered around it. The background is a light green and yellow gradient with a large, faint green leaf shape on the left side.

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RANDOMIZED CONTROLLED TRIAL OF SAINDHAVADI ASCHYOTAN (EYE DROPS) IN THE MANAGEMENT OF SHUSHKAKSHIPAK, WITH SPECIAL REFERENCE TO DRY EYE SYNDROME - A PILOT STUDY.

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ABSTRACT:

Background: When your tears are unable to adequately lubricate your eyes, dry eye disease, a common illness, develops. There are various reasons why tears may be insufficient and unsteady. For instance, dry eyes may develop if your tear production is inadequate or of poor quality. This condition in Ayurveda can be correlated with Shushkaakshipaak. **Objective:** To compare the effect of Saindhavadi Eye Drops and Polyethylene Glycol 400 + Propylene Glycol Eye Drops in management of shushkaakshipaak w.s.r. Dry Eye Syndrome. **Methodology:** In this pilot study, total 10 patients of Shushkakshipak (Dry Eye Syndrome) were selected and given Saindhavadi Aschyotan (Eye Drops) in the dose of 10 drops each eye for Group-A while in Group-B, Polyethylene Glycol 400 + Propylene Glycol Eye drops were administered for 21 days and follow up were taken on 7th and 21 days. **Results & Conclusion:** In this pilot study, it was observed that both the intervention was found to be equally effective. However, the Saindhavadi Aschyotan is prepared from various herbal ingredients which is having soothing effect on eyes and can be recommended in the management of Shushkakshipak (Dry Eye Syndrome).

KEYWORDS: - Shushkakshipak, Saindhavadi Aschyotan, kruchounmilan, dry eye syndrome

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INTRODUCTION:

Ayurveda describes a condition called Shushkaakshipaak in the classical literature under Sarvagata Netrarog.^[1] The lakshanas of Shushkaakshipaak are rukshata (Dryness), daah (Burning sensation), avildarshan (Blurring of Vision), kruchounmilan (Unable to open eyes easily).^[2] The lakshanas of Shushkaakshipaak can be equated with the signs and symptoms of Dry Eye Syndrome. The symptom of dry eye includes irritation, foreign body sensations, feeling of dryness, itching, non-specific ocular discomfort, conjunctival xerosis, reduced or absent marginal tear strip and corneal changes in the form of punctate epithelial erosions and filaments.^[3] It is a very common condition characterized by disturbances of tear film. Approximately 18.4 % to 54.3% of the world population is suffering with this disease.^[4] Tear secretion provides continuous moisture and lubrication on the ocular surface to maintain comfort, corneal and conjunctival health, and vision. Abnormalities of any of the components of the secretion lead to the instability of the tear film, resulting in drying of the ocular surface. Tear substitutes are the

only treatment modality with modern medical science. The duration of action of these tear substitutes is variable and are advised as per the need, only providing symptomatic relief. The preservatives present in these formulations are also a cause of dry eye, whereas those available without preservatives are not cost effective. Hence there is a need to find a safe and effective medication. [5]

Aim: To compare the effect of Saindhavadi Aschyotan (Eye Drops) and Polyethylene Glycol 400 + Propylene Glycol Eye Drops in management of Shushkaakshipaak w.s.r. Dry Eye Syndrome.

Primary Objectives:

- 1.To evaluate the efficacy of Saindhavadi Aschyotan in management of Shushkaakshipaak.
- 2.To evaluate the efficacy of Polyethylene Glycol 400 and Propylene Glycol Eye Drops.

Methodology: Study Design: Randomized Control Trial-a pilot study.

Study Setting: Study were carried out in OPD and IPD of Teaching Hospital. Study duration:Total study duration will be 1 month.

Table no. 1 Group management:

Sr. No.	Subject	Group A	Group B
1.	Drug	Saindhavadi Aschyotan (Eye Drops)	Polyethylene Glycol 400 and Propylene Glycol Eye drops
2.	Matra	10 drops	2 drops
3.	Dharana Kala	1000 vaakmatra (10 min)	10 minutes
4.	Treatment duration	21 days	21 days
5.	Follow-up	Follow up 0, 7 th , 21 st day	Follow up 0, 7 th , 21 st day
6.	Sample size	10	10

Randomization/Allocation concealment:

Total Selected 10 patients were randomly distributed into two equal groups each comprising 10 patients.

Method of Selection of Study Subject:**Inclusion Criteria: -**

1. Patients willing for trial with written and informed consent.
2. Gender – Irrespective of gender
3. Patients aged between 18-60
4. Patients having following symptoms: Rukshata (Dryness), Daah (Burning

sensation), Avildarshan (Blurring of Vision), Kruchounmilan (Unable to open eyes with easily)

Exclusion Criteria: -

1. Congenital anomalies of eye., Abnormal structure and function of eyelid.

2. Abhighataj Netrarog - Injuries (Mechanical/Clinical)

3. Patients who are using drugs like antihistamines, decongestants, hormonal therapy, antidepressants, dermatologic medications, antipsychotic medications, and chemotherapy medications.

Methods of Measurement:

1. Dryness of Eyes (Rukshta):

Character	Characteristic	Score
No dryness of eyes	which is greater than or equal to 15 mm wetting of paper after 5 min	0
Mild dryness	This is 14-9 mm 15 mm wetting of paper after 5 minutes	1
Moderate dryness	This is 8 - 4 mm 15 mm wetting of paper after 5 minutes	2
Severe dryness	This is less than 4 mm 15 mm wetting of paper after 5 minutes	3

2. Blurring of eyes (Avildarshan)-

Character	Characteristic	Score
No blurring of vision	No Problem to Read	0
Mild blurring of vision	Mild problem to read	1
Moderate blurring of vision	Vision near about 6/9	2
severe blurring of vision	Vision near about 6/12	3

3. Unable to open eyes easily (kruchounmilan)-

Character	Score
No difficulty in opening of eyes	0
Mild difficulty in opening eyes	1
Moderate difficulty in opening eyes	2
severe difficulty in opening eyes	3

4. Burning of eyes (Daah):

Character	Score
No burning of eyes	0
Mild burning of eyes (Burning eyes for few min in day)	1
Moderate burning of eyes (Burning eyes for 1-2 hrs in day)	2
Severe burning of eyes (Burning eyes Whole day)	3

Objective Criteria-

Schirmer's test done before and after.

1. Normal - which is greater than or equal to 15 mm wetting of paper after 5 min.
2. Mild - This is 14-9 mm 15 mm wetting of paper

after 5 minutes.

3. Moderate - This is 8 - 4 mm 15 mm wetting of paper after 5 minutes.
4. Severe - This is less than 4 mm 15 mm wetting of paper after 5 min.

Observation & Results:**Table no. 2 Wilcoxon signed rank test for subjective criteria in Group -A**

Sr.no.	Symptoms	Mean		SD		Median		p value
		BT	AT	BT	AT	BT	AT	
1	Dryness of Eyes (Rukshta)	2.30	0.80	0.48	0.79	2	1	<0.0001
2	Blurring of eyes (Avildarshan)	1.20	0.60	1.14	0.70	1.5	0.5	<0.0001
3	Unable to open eyes easily (kruchounmilan)	1.80	0.50	0.79	0.53	2	0.5	<0.0001
4	Burning of eyes (Daah)	1.40	0.00	0.97	0.00	1.5	0	<0.0001

Table no. 3 Wilcoxon signed rank test for subjective criteria in Group -B

Sr.no.	Symptoms	Mean		SD		Median		p value
		BT	AT	BT	AT	BT	AT	
1	Dryness of Eyes (Rukshta)	2.10	1.10	0.57	0.74	2	1	<0.0001
2	Blurring of eyes (Avildarshan)	1.60	0.70	1.17	0.67	2	1	<0.0001
3	Unable to open eyes easily (kruchounmilan)	2.30	0.40	0.48	0.52	2	0	<0.0001
4	Burning of eyes (Daah)	1.50	0.10	0.97	0.32	2	0	<0.0001

Table no .4 Comparison between group for the subjective criteria by Mann Whitney Test

Sr.no.	Symptoms	Mean		SD		Median		Mann Whitney		p value
		Gr-A	Gr-B	Gr-A	Gr-B	Gr-A	Gr-B	U'	U	
1	Dryness of Eyes (Rukshta)	1.50	1.00	0.85	0.94	1.5	1	67	33	0.2074
2	Blurring of eyes (Avildarshan)	0.60	0.90	0.97	1.10	0	1	60	40	0.4695
3	Unable to open eyes easily (kruchounmilan)	1.30	1.90	0.95	0.74	1	2	56.5	24.5	0.1661
4	Burning of eyes (Daah)	1.40	1.40	0.97	0.84	1.5	2	51	49	0.9694

Table no. 5 Wilcoxon signed rank test for Objective criteria in Group -A

Sr.no.	Symptoms	Mean		SD		Median		p value
		BT	AT	BT	AT	BT	AT	
1	Schirmer's test	1.60	0.60	0.51	0.51	2.0	1.0	0.003

Table no. 6 Wilcoxon signed rank test for Objective criteria in Group -B

Sr.no.	Symptoms	Mean		SD		Median		p value
		BT	AT	BT	AT	BT	AT	
1	Schirmer's test	1.90	0.90	0.56	0.31	2.0	1.0	0.003

Table no.7 Comparison between group for the Objective criteria by Mann Whitney Test

Sr.no.	Symptoms	Mean		SD		Median		Mann Whitney		p value
		Gr-A	Gr-B	Gr- A	Gr- B	Gr- A	Gr-B	U'	U	
1	Schirmer's test	1.00	1.00	0.47	0.47	1.00	1.00	50	50	0.96

DISCUSSION:

In this pilot study, total 10 patients of Shushkakshipak (Dry Eye Syndrome) were selected and given Saindhavadi Aschyotan (Eye Drops) in the dose of 10 drops each eye for Group-A while in Group-B, Polyethylene Glycol 400 and Propylene Glycol Eye drops were administered for 21 days and follow up were taken on 7th and 21 days, and actual effect of therapy was observed on 21st day of the intervention. It was observed that in Group-A for the symptoms, Dryness of Eyes (Rukshta), Blurring of eyes (Avildarshan), Unable to open eyes easily (kruchounmilan) and burning of eyes (Daah) the effect of therapy was seen significant as p value is observed is <0.005 which is considered as highly significant. Similarly, the effect of therapy was also seen significant for these symptoms in Group- B also as p value is observed is <0.005 which is considered as highly significant. In objective criteria, Schirmer's test was done to assess the result in each group before and after treatment. It was observed in the Group-A the p value was significantly statistically as it is <0.005, similarly it was also significant in Group-B also. After comparison of results of therapy between the groups in the subjective criteria, it was observed that p value was observed was >0.05 in the symptoms like Dryness of Eyes (Rukshta), Blurring of eyes (Avildarshan), Unable to open eyes easily (kruchounmilan) and burning of eyes (Daah), it means the

intervention of both the group was found to be equally effective. Similarly for the objective criteria Schirmer's test p value was >0.05 which mean tha the intervention was equally effective in the management of Shushkakshipak, with special reference to Dry Eye Syndrome.

CONCLUSION:

In this pilot study, total 10 patients of Shushkakshipak (Dry Eye Syndrome) were selected and given Saindhavadi Aschyotan (Eye Drops) Group-A while in Group-B, Polyethylene Glycol 400 and Propylene Glycol Eye drops were administered for 21 days, after analysis it was observed that both the intervention was found to be equally effective. However the Saindhavadi Aschyotan is prepared from various herbal ingredients which is having soothing effect on eyes and also not having any adverse effects. So, it can be recommended in the management of Shushkakshipak (Dry Eye Syndrome).

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