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EFFICACY OF INTEGRATED OCULAR AND SYSTEMIC AYURVEDIC THERAPY IN POST-MENOPAUSAL DRY EYE (SHUSHKAKSHIPAKA): A RANDOMIZED COMPARATIVE TRIAL.

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ABSTRACT

Background: Dry Eye Disease (DED) is a multi-factorial ocular surface disorder frequently observed in post-menopausal women due to changing hormonal statuses, particularly decreased androgen and estrogen levels affecting the lacrimal and meibomian glands. In Ayurveda, this condition can be correlated with Shushkakshipaka, classified under Vata-Pittaja dominant Sarvagata netra roga.

Objective: To evaluate and compare the clinical efficacy of a combined therapy using Drakshadi Ghrita Aschyotana (medicated eye drops) and internal Shatavari Ksheerapaka versus internal Shatavari Ksheerapaka alone in post-menopausal women suffering from Dry Eye Disease.

Methodology: A comparative clinical trial with a pre- and post-test design was conducted on a minimum of 40 post-menopausal women aged 45 to 55 years fulfilling the inclusion criteria. Patients were equally divided into two groups of 20 subjects each.

Group A (Trial): Treated with Drakshadi Ghrita Aschyotana (10 drops in each eye once daily) combined with internal Shatavari Ksheerapaka(2 phala in divided doses) for 60 days.

Group B (Standard): Treated with internal Shatavari Ksheerapaka (2 phala in divided doses) alone for 60 days. Assessment criteria included subjective parameters via the Ocular Surface Disease Index (OSDI) and objective parameters including Schirmer's test and Tear Break-Up Time (TBUT), evaluated across four follow-up intervals over 60 days.

Results: Both groups showed statistically significant improvements from baseline to after-treatment in Schirmer's test and TBUT parameters ($p < 0.001$). However, Group A (Trial) demonstrated a statistically highly significant greater improvement, with a 45.1% increase in Schirmer's test scores (compared to 34.8% in Group B) and a 45.4% increase in TBUT scores (compared to 42.2% in Group B). Overall response rates analyzed via the Mann-Whitney U Test confirmed that Group A performed significantly better overall ($p < 0.001$, $Z = 3.71$).

Conclusion: The combined therapy of Drakshadi Ghrita Aschyotana and internal Shatavari Ksheerapaka is significantly more effective than internal Shatavari Ksheerapaka alone in managing Dry Eye Disease in post-menopausal women, offering synergistic benefits through localized ocular lubrication, anti-inflammatory properties, and hormonal regulation.

KEYWORDS: Dry Eye Disease (DED); Shushkakshipaka; Post-menopausal women; Drakshadi Ghrita Aschyotana; Shatavari Ksheerapaka; Ayurveda; Schirmer's test; Tear Break-Up Time (TBUT); Ocular Surface Disease Index (OSDI); Meibomian glands; Lacrimal glands; Vata-Pittaja Netra Roga.

INTRODUCTION

Menopause is common natural transition phase in women's life in which the body greatly reduces the female sex hormones. In this stage women suffers from various symptoms like hot flushes, moodswings, night sweats, vaginal dryness and also dryness of eyes. These will greatly affect & incapacitate the sufferer. Though majority of menopausal women suffer (i.e 60%) often, problem is not addressed properly. The changing hormonal status, i.e decreased androgen hormone affects meibomian and lacrimal glands in the eye lids. This results in Dry eye disease.

Dry eye disease is one of the common disorders that may lead to visual impairment & severe ocular complications in later stages. Postmenopausal women are one of the most common groups to be affected by dry eye[(1)].

The DRY EYE DISEASE is multi factorial ocular surface disorder usually caused by chronic inflammation and characterized by tear film instability and increased osmolarity. There are various symptoms in Dry eye disease patients, such as ocular discomfort, fluctuating visual disturbances, and potential damage.

Large epidemiological studies documented the prevalence of dry eye disease (DED) from five to over 30%[(2,3)]. Again when we see the incidence of DRY EYE DISEASE in menopausal women, Epidemiologic studies showed it is more prevalent among women, particularly post-menopausal and elderly population[(4)].

According to Ayurveda classics Shushkakshipaka, Vata-Pittaja pradhana Sarvagata netra roga. It is a vata pittaja sadhya vyadhi[5]. The clinical features of Shushkakshipaka can be correlated with Dry eye disease. Ayurveda offers various treatment modalities including external therapies and internal medications.
The probable mode of action of drakshadi ghrita[6] aschyotana is it alleviates netragata Vata & Pitta by means of properties like madhura rasa, sheeta veerya and chakshushya effects. The Shatavari ksheerapaka being jeevaneeya and chakshusya, it alleviates Vata and Pitta. As shatavari contains phyto oestrogen[7], it also helps in regulation of oestrogen in general thus helps in management of Dry eye disease in post menopausal women.
Considering all these factors present study i.e. combined Effect of Drakshadi Ghrita Aschyotana and Shatavari ksheerapaka paana internally versus shatavari ksheera paka paana internally in post menopausal women with Dry eye disease is taken up.

METHODOLOGY:

MATERIALS AND METHODS:
Study design: Comparative clinical study.
Source of data: Patients will be selected from OPD of BVVS Ayurved Medical College & Hospital, Bagalkot.
Sample size: Minimum of 40 patients fulfilling inclusion criteria will be included with dry eye disease in present study which will be divided in 2 groups, each group consisting 20 patients.
Study site: BVVS Ayurved Medical College and Hospital- Bagalkot.
Inclusive criteria:
Women with complaints of Dry eye disease aged in between 45 -55 years with menstrual cessation for at least one year.
Menopausal Women with Dry eye disease complaints & willing to participate in the study.

Exclusive criteria:
Women below 45 years.
Recurrent eye inflammation.
History of trauma.
History of eye surgery within three months
Systemic illness including DM, HTN, PCOS
Malignancy, Psychiatric diseases other uro-genital diseases.
Women underwent surgical management for complete hysterectomy.

Intervention
1. Drug:
Method of preparation and place: The trial drug will be prepared at BVVS Ayurved Medical College Pharmacy as per classical methods.
Drakshadi Ghrita for aschotana[8]
Method of Preparation

Ingredients:

S No	Drug	Botanical Name
1.	Draksha	Vitis vinifera
2.	Chandana	Santalum album
3.	Manjishtha	Rubia cordifolia
4.	Ashwagandha	Withania somnifera
5.	Vidari	Pueraria tuberose
6.	Sita (Sharkara)	Sugar
7.	Shatavari	Asparagus racemosus
8.	Pundrahva	Saccharum officinarum
9.	Madhuka	Glycerrhiza glabra
10.	Utpala	Nymphaea stellata
11.	Goghrita	Cow Ghee
12.	Godugdha	Cow Milk

Method of preparation of Drakshadi Ghrita for Aschyotana.
After collecting all the ingredients of Drakshadi Ghrita in a large vessel Go-Ghrita was poured, when it liquefied under moderate flame, Kalka of Draksha, Chandana, Manjishtha, Ashwagandha, Vidari, Sita (Sharkara), Shatavari, Pundrahva, Madhuka, Utpala was added, followed by addition of cow milk. To get final product, the contents were subjected to moderate heat till up to Sneha Siddhi (properly prepared medicated Ghee) features.
Dosage: 10 drops in each eye once daily
Duration: 60 days.

Method of preparation of Shatavari ksheerapaka for internal administration.

According to Sharangdhara Samhita, Ksheerapaka (medicated milk) is prepared with one part of Shatavari choorna, eight parts of milk and 32 parts of water(1:8:32). Mixture is heated on moderate heat and boiled till only milk part remains in the vessel[9]

Dosage: 2 pala in two divided doses.

Duration: 60 days.

Assessment criteria:

It is based on comparison of pre and post test assessment of subjective and objective parameters

Subjective parameters: Ocular Surface Disease Index for the diagnosis of dry eye[10].

Ref: PMCID: PMC5339423

PMID: 28321333

Objective Parameters:

Schirmer's test.

TBUT

Treatment plan :

Duration : 60 days

Follow up study: 4 follow ups with 15 days intervals

RESULTS

1. Schirmer's Test

Effect of treatment within the GROUP A (Trial) on Schirmer's Test

The statistical analysis of the treatment effect for each paired observation within Group A (Trial) on Schirmer's Test:

It compares baseline (BT) and after-treatment (AT) mean values, highlighting the magnitude of change, percentage of increase, and statistical significance using the Paired samples t-Test, for the sample size (20).

In the **Group A (Trial) treatment for Schirmer's Test**, the BT mean ±SD value was 7.00 ±1.26 which increased to 12.75 ±1.41 units After Treatment. This corresponds to mean difference of 5.75 with a substantial 45.1% of increase in Schirmer's Test from BT to AT.

The Paired Samples t-Test results show that, SE of mean for BT = 0.281 and AT = 0.315 with t-value 25.22 which shows highly significant ($p<0.001$) increase in Schirmer's Test.

In summary, the treatment applied within Group A (Trial) findings suggest that; from BT to AT there is statistically highly significant 45.1% of increase is observed on Schirmer's Test parameter.

Effect of treatment within the GROUP B (Standard) on Schirmer's Test

The statistical analysis of the treatment effect for each paired observation within Group B (Standard) on Schirmer's Test:

It compares baseline (BT) and after-treatment (AT) mean values, highlighting the magnitude of change, percentage of increase, and statistical significance using the Paired samples t-Test, for the sample size (20).

In the Group B (Standard) treatment for Schirmer's Test the BT mean ±SD value was 6.65 ±1.60 which increased to 10.20 ±1.77 units After Treatment. This corresponds to mean difference of 3.55 with a substantial 34.8% of increase in Schirmer's Test from BT to AT. The Paired Samples t-Test results show that, SE of mean for BT = 0.357 and AT = 0.395 with t-value 9.17 and which shows highly significant ($p<0.001$) increase in Schirmer's Test.

In summary, the treatment applied within Group B (Standard) findings suggest that; from BT to AT there is statistically highly significant 34.8% of increase is observed on Schirmer's Test parameter.

Comparisons Between Group A (Trial) with Group B (Standard) in Schirmer's Test.

The comparisons between Group A (Trial) with Group B (Standard) concerning the Schirmer's Test variable After Treatment. It highlights the mean values, standard deviations, and standard errors for each group, along with the mean difference, percentage difference, and statistical significance using the Independent samples t-test between the two groups.

The comparison of Schirmer's Test observations shows that, Group A (Trial) recorded a mean score of 12.75 ±1.41, while Group B (Standard) showed a lower mean of 10.20 ±1.77. The mean difference between the two groups was 2.55 points, corresponding to a 20.0% improvement in favour of GROUP A (Trial). Statistical analysis using the independent samples t-test yielded a test statistic t-value of 5.05. That denoting a highly significant ($p<0.001$) difference between the two groups in terms of Schirmer's Test after Treatment period.

In summary, based on the Independent Samples t-Test results there are real statistically significant differences observed between the groups regarding the Schirmer's Test variable. The comparison of AT observations indicates a Highly Significant 10.29% difference between the groups. Based on the mean values we can say that Group A (Trial) in improvement is statistically highly significantly better than Group B (Standard).

2. TBUT

Effect of treatment within the GROUP A (Trial) on TBUT

The statistical analysis of the treatment effect for each paired observation within Group A (Trial) on TBUT are presented in Table. It compares baseline (BT) and after-treatment (AT) mean values, highlighting the magnitude of change, percentage of increase, and statistical significance using the Paired samples t-Test, for the sample size (20).

In the Group A (Trial) treatment for TBUT, the BT mean ±SD value was 5.30 ±0.92 which increased to 9.70 ±1.42 units After Treatment. This corresponds to mean difference of 4.4 with a substantial 45.4% of increase in TBUT from BT to AT. The Paired Samples t-Test results show that, SE of mean for BT = 0.206 and AT = 0.317 with t-value 19.78 which shows highly significant ($p<0.001$) increase in TBUT.
In summary, the treatment applied within Group A (Trial) findings suggest that; from BT to AT there is statistically highly significant 45.36% of increase is observed on TBUT parameter.

Effect of treatment within the GROUP B (Standard) on TBUT

The statistical analysis of the treatment effect for each paired observation within Group B (Standard) on TBUT are presented in Table. It compares baseline (BT) and after-treatment (AT) mean values, highlighting the magnitude of change, percentage of increase, and statistical significance using the Paired samples t-Test, for the sample size (20).
In the Group B (Standard) treatment for TBUT the BT mean ±SD value was 5.00 ±1.34 which increased to 8.65 ±1.46 units After Treatment. This corresponds to mean difference of 3.65 with a substantial 42.2% of increase in TBUT from BT to AT. The Paired Samples t-Test results show that, SE of mean for BT = 0.299 and AT = 0.327 with t-value 8.72 and which shows highly significant ($p<0.001$) increase in TBUT.
In summary, the treatment applied within Group B (Standard) findings suggest that; from BT to AT there is statistically highly significant 42.2% of increase is observed on TBUT parameter.

Comparisons Between Group A (Trial) with Group B (Standard) in TBUT.

This table involves comparisons between Group A (Trial) with Group B (Standard) concerning the TBUT variable After Treatment. It highlights the mean values, standard deviations, and standard errors for each group, along with the mean difference, percentage difference, and statistical significance using the Independent samples t-test between the two groups.
The comparison of TBUT observations shows that, Group A (Trial) recorded a mean score of 9.70 ±1.42, while Group B (Standard) showed a lower mean of 8.65 ±1.46. The mean difference between the two groups was 1.05 points, corresponding to a 10.8% improvement in favour of GROUP A (Trial). Statistical analysis using the independent samples t-test yielded a test statistic t-value of 2.31. That denoting a moderately significant ($p<0.05$) difference between the two groups in terms of TBUT After Treatment period.
In summary, based on the Independent Samples t-Test results there are real statistically significant differences observed between the groups regarding the TBUT variable. The comparison of AT observations indicates a Moderately Significant 3.16% difference between the groups. Based on the mean values we can say that Group A (Trial) in improvement is statistically moderately Significantly better than Group B (Standard).

Overall response After Treatment

In both the groups, GROUP-A and GROUP-B, there were no subjects at all who are coming under a No Response, defined as a response rate ranging between (0%-1%) respectively After Treatment.
Afterwards if we consider a Poor Response, which ranges from (1%-25%), GROUP-A has 0 subjects, accounting for 0% of the group. Then, if we consider GROUP-B, which had 3 subjects, or 15% showing under Poor Response category.
When considering a Mild Response category, which ranges from (25%-50%), GROUP-A has 4 subjects, accounting for 20% of the group. Likewise GROUP-B, which had 12 subjects, or 60% showing under Mild Response category.
Then for a Moderate Response category, which ranges between (50%-75%), GROUP-A has 15 subjects, representing 75% of the group, while GROUP-B has 5 subjects, which is 25% of the group.
Lastly, for a Marked Response category, which ranges between (75%-100%), GROUP-A has 1 subject, representing 5% of the group, while GROUP-B has 0 subjects, After Treatment.
Overall Response After Treatment data shows that GROUP-A and GROUP-B have much differences in response distributions. GROUP-A had no subjects in the poor response, less subjects mild response category and a slightly higher proportion in the moderate response category compared to GROUP-B. Additionally, GROUP-A had a higher percentage of marked responses. While GROUP-B had three subjects in poor response and larger proportion of mild responses.
The Mann-Whitney U Test for independent groups, is used to assess the overall differences between the two groups GROUP-A and GROUP-B at the completion of After Treatment by considering combined observations of all the parameters. The findings; test statistic (U) is calculated as 63.5, and the corresponding Z-value is 3.71. The p-value for this comparison is reported as $p < 0.001$, denoting a statistically Highly Significant differences between the groups, with a large effect size of $r= 0.59$ of result. GROUP-A is very much better by 17%, which is statistically Highly significant. Hence, GROUP-A (Trial) is much better than GROUP-B (Standard) in effectiveness of the drug/treatment/therapy.

DISCUSSION

Dry eye disease is more prevalent in women after menopause and hormonal alterations have been implicated in its pathophysiology[11,12].
Experimental studies have observed sex hormone receptors in the lacrimal and meibomian glands[13]. Clinical observations have reported associations between hormonal deficiency states and impaired tear production[14]. The outer layer of the tear film lipid layer (TFLL) also known as the air-water interface, is mainly made up of lipids that keep the ocular surface from drying up and from evaporating water while also giving the cornea a smooth visual surface. In addition to being crucial for tear surface tension, the lipid, wax esters and protein components of the TFLL are also necessary for ocular homeostasis and the physiological hydration of the ocular surface.Collectively, these findings support the role of sex hormones in maintaining ocular surface homeostasis and tear film integrity.

The plant commonly known as shatavari or Satmuli (Asparagus racemosus), belongs to the family Liliaceae. Shatavari is rich in active constituents such as steroidal glycosides, saponins, polyphenols, flavonoids, alkaloids (racemosol), and vitamins. Shatavari is a classical Ayurvedic Rasayana widely used in women's health. Phytochemical investigations have identified several constituents, including rutin, kaempferol, genistein, daidzein, and quercetin, that exhibit estrogen receptor-binding activity in experimental models[15].Clinical studies have also reported improvements in menopausal symptoms and quality of life following Shatavari supplementation[16].

Aschyotana (Medicated eye drop instillation) is traditionally considered as a primary intervention in acute ocular conditions, as it allows direct delivery of therapeutic agents to the ocular surface.

Drakshadi gritha contains phytoconstituents like Resveratrol and anthocyanins act as powerful free-radical scavengers. They inhibit the expression of pro-inflammatory cytokines (such as Interleukin-6 and TNF-alpha), thereby protecting the corneal epithelium from apoptosis and reducing redness and burning sensations.

Triterpenoid Saponins & Glycosides exert a potent anti-inflammatory action that mimics mild corticosteroids without the adverse side effects. Glycyrrhizin helps retain moisture on the ocular surface by mitigating inflammatory tissue damage to the conjunctival goblet cells, which are responsible for secreting the crucial mucous layer of the tear film.

As Gritha contains fatty acids, antioxidant constituents, and fat-soluble vitamins which have been proposed to support ocular surface lubrication and epithelial integrity [17,18]Additionally, ghee forms a rich source of fat-soluble vitamins (vitamin A & E) and β-carotene which is found to exhibit anti-inflammatory properties by reducing the factor-α and interleukin-6 levels. Previous studies have suggested that dietary omega-3 fatty acids may improve tear film stability and reduce ocular surface inflammation[19].

Both study groups additionally received Shatavari Ksheerapaka pana as systemic therapy. As Shatavari has traditionally been described as a Rasayana.

The better improvement observed in the Drakshadi Ghrita aschyotana with shatavari ksheerapaka pana than Shatavari ksheerapaka pana alone.

CONCLUSION

Therefore, the findings of this study suggest that Shatavari Ksheerapaka pana when used in combination with Drakshadi Ghrita eye drops, may provide better clinical benefit than only Shatavari Ksheerapaka pana for improving dry eye symptoms and tear film parameters in postmenopausal women. Further studies with longer follow-up and investigations are warranted to confirm these findings.

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