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ORIGINAL ARTICLE

Efficacy of Yashtimadhu Ghrita *Tarpana* in the Management of *Sushkakshipaka* (Dry Eye Syndrome): A single-arm clinical trial

Syam Chandran C.[1*], Manjiri keskar [1], Unni Krishnan[2] and Arun G Dev [3]
[*1]Department of Shalakya Tantra, Parul Institute of Ayurveda, Parul University, Vadodara, Gujarat Pin: 391760
[2]MS(Shalakya), Managing Director, Vaidhyanath Ayurveda Hospital, Kollam, Kerala.
[3] Medical Officer Shalakya, National Ayush Mission, Allepy, Kerala
Correspondence Author: Syam Chandran C
Email: drsyamchandran3@gmail.com

ABSTRACT
A prevalent ocular ailment called dry eye disease (DED) results from insufficient tear film support for the biological functions of the ocular surface. Tear hyperosmolarity may result from extrinsic environmental stress; intrinsic cerebral, or endocrinological variables that decrease aqueous tear flow or increase tear film evaporation. It is critical to address the underlying cause of ocular surface inflammation in order to stop the advancement of dry eye. Individuals suffering from DED often report irritated eyes, variable-day blurring of vision, and even photophobia. Sushkakshipaka is one among "Sarvagata Netra Rogas" mentioned by Sushruta as well as Vagbhata under Sadhya Netra Roga, caused by Vata and Pitta having symptoms of Gharsha, Toda, Bheda, Upadeha, Krichronmeelan, Vishushkata, Rooksha Daruna Vartma, etc., these symptoms can be equated with the symptoms of Dry Eyes in modern system of medicine. One of the major Kriyakalpa that nourishes the eyes and treats Vata Pitta ailments is Tarpana . Because of its Snehana and Vata and Pitta hara actions, it might be quite helpful in managing Sushkakshipaka. In this current study yashtimadhu siddha ghritha in the form of Tarpana was given as the treatment for screened patients. The ingredients include yashtimadhu, ghritha, ksheera, jala and sarkara, which are predominantly vatapittahara. Effect of Yashtimadhu Ghruta Tarpana is found to be significantly effective in reducing the signs and symptoms of Sushkakshipaka .
Keywords*: Dry eye; Netraroga; Sushkakshipaka ; Tarpana ; Yastimadhusiddha gruta.*

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INTRODUCTION

Dry eye disease, a common ocular condition, arises when the tear film does not adequately support biological functions of the ocular surface. This can arise due to extrinsic environmental stress; intrinsic cortical and endocrinological factors that reduce aqueous tear flow and or increase tear film evaporation, leading to tear hyperosmolarity [1]. Tear hyperosmolarity triggers an inflammatory cascade on the ocular surface, causing release of inflammatory mediators into tears, epithelial damage, and tear film instability. To arrest progression of dry eye, it is important to address the underlying mechanism of ocular surface inflammation [2]. DED is not merely due to reduced tear volume. It is a multi-factorial disease of the tear and ocular surface that arises when the pre-ocular tear film does not adequately support biological functions of the ocular surface. This arises due to environmental or endogenous stress, microbial insult or genetic factors. Acute inflammatory pathways of the ocular surface are triggered with tear dysfunction and hyperosmolarity, and this potentiates a chronic inflammatory cycle that is seen in DED. Such inflammatory pathways are driven by host ocular immunity [3]. Patients with DED experience varying severity of symptoms. Most patients complain of eye irritation, blurring of vision that fluctuates across the day and even photophobia. DED significantly reduces the quality of life among those affected. *Sushkakshipaka* is one among "*Sarvagata Netra Rogas*" mentioned by *Vagbhata* [4] as well as *Sushruta* [5] under *Sadhya Netra Roga,* caused by *Vata* and *Pitta* having symptoms of *Gharsha, Toda, Bheda, Upadeha,*

Krichronmeelan, Vishushkata, Rooksha Daruna Vartma, etc., These symptoms can be equated with the symptoms of Dry Eyes in modern system of medicine [6]. *Tarpana* is one among the important *Kriyakalpa* which gives nourishment to the eyes and cures the *Vata Pitta* diseases. It may be very much useful in the management of *Sushkakshipaka* due to its *Snehana* and *Vata* and *Pittahara* actions [7]. In this current study *yashtimadhu siddha ghritha* in the form of *Tarpana* was given as the treatment for screened patients. The ingredients include *yashtimadhu, ghritha, ksheera, jala* and *sarkara,* which are predominantly *vatapittahara*. The drug *yashtimadhu* has the properties like *chakshushya, rasayana* and *bruhmana* which are beneficial in curing the pathological manifestation involved in *sushakshipaka*, mainly by its *vatapittahara* property. The lipid soluble principles herbal drugs active principles may cross the lipophilic barrier of the corneal epithelium and reach the target site. Due to the more tissue contact time, the absorption rate is also more [8]. Especially in the Chronic conditions were *dosha* dominance is *vata paitika*, the therapy is more indicated.

MATERIAL AND METHODS

31 Patients were selected from Out-patient department and In-patient department of *Shalakya Tantra*, SDM college of Ayurveda and Hospital, Hassan; who is fulfilling the criteria for diagnosis and inclusion were selected for the present study irrespective of sex and duration of the disease (each eye considered individually i. e. 62 eyes). A random selection of thirty-one patients who exhibit the symptoms of *Shuskakshipaka* had given two consecutive sittings of *Tarpana* with *Yashtimadhu Ghrita* continuously for seven days at intervals of fifteen days. Following the completion of the second course of *Tarpana*, follow-up visits will be made at intervals of fifteen days for duration of two months. Diagnostic criteria: Clinical characteristics of *Sushkakshipaka* (Dry Eye Syndrome); *Gharsha* (Friction/sensation of dirt in the eyes); Toda (Pricking pain); *Krichronmeelanimeelana* (Difficulty in opening and closing of eyelids); *Rooksha vartmakshi* (Dryness of ocular and lid); *Daruna Vartmakshi* (eyelid and eye pain); *Vikoonana* (Photophobia / Discomfort and sensitivity to bright light); *Raktharaji* (Congestion); *Daha* (Burning sensation); *Upadeha* (Stingy mucous discharge)

Inclusion criteria: All patients exhibiting *Sushkakshipaka* signs and symptoms, regardless of their age, sex, caste, religion, socioeconomic level, or chronicity, were included in the clinical investigation; Age range of 10 to 60 years; Patients prepared to sign an informed consent. Exclusion criteria: Chemical and Mechanical Injuries (*Abhighataja Netra Roga*); Systemic conditions such as Sjogren's syndrome, SLE, and rheumatoid arthritis; Individuals receiving medication for dermatology, antipsychotics, hormone therapy, antidepressants, decongestants, antihistamines, and chemotherapy;

Congenital Alacremia; Correlated with glaucoma and other disorders, as well as any inflammatory or infectious ocular diseases.

***Tarpana* procedure**: The Eyes are cleaned with sterile cotton by dipping it in lukewarm water, and a concentric boundary will be made along the outer orbital margin with paste of *Masha Choorna*. Approximately 20ml (till it covers the tip of eyelashes) of lukewarm *Yashtimadhu Ghrita* was filled in both eyes and allowed to remain in the eyes for approximately 25 minutes, i.e., 1000 *Matra kala,* and the patient is allowed to close and open the eyes frequently. After the prescribed time, *ghrita* was removed by making a hole in the boundary at the lateral canthus of the eye, followed by the removal of the boundary, and the eyes were cleansed, and *Akshibandhana* will be performed for 1 hr. Evaluation Criteria: Utilizing a self-developed grading system, the assessment has been based on how well the signs and symptoms are improving; *Sushkakshipaka* (Dry Eye Syndrome) was evaluated using both subjective and objective measures, both before and after therapy, using the proper statistical technique. Subjective Parameters: subjective parameters were assisted by gradation from 0 to 3 before and after treatment. The aggravating factors, like Environmental factors, routine work, and relieving factors, like rest, medicine, washing with water, dark room, and rubbing of eyes, were also assisted by communicating with the patient.

Table 1: gradation details of subjective criteria.

Sr. No.	Parameter	Gradation
1.	*Gharsha* (Friction / sensation of dirt in the eyes)	0-Absent 1-occasionally present 2-Frequently present 3-Continuously Present throughout the day
2.	*Toda* (Pricking pain)	0-Absent 1-Occassionaly Present 2-Frequently Present 3- Continuously Present throughout the day

3.	*Krichronmeelanimeelana* (Difficulty in opening and closing of eye lids)	0-Absent 1-Occassionaly Present 2-Frequently Present 3- Continuously Present throughout the day
4.	*Rooksha vartmakshi* (Dryness of eyelid and eye)	0-Absent 1-Occassionally Present 2-Frequently Present 3-Continuously Present throughout the day
5.	*Daruna Vartmakshi* (Painful eyelid and eye)	0-Absent 1-Occassionally present 2-Frequently Present 3- Continuously Present throughout the day
6.	*Vikoonana* (Photophobia)	0-Absent 1-Sensitive to very bright light 2-Sensitive to mild bright light 3-Sensitive to dim light
7.	*Raktharaji* (Congestion)	0-Absent 1-Discrete, thin vessels limited to Palpebral Conjunctiva and Fornix conjunctiva 2-Prominat vascular network involving the peripheral part of Bulbar conjunctiva 3-Fiery red eye involving the whole parts of conjunctiva
8.	*Daha* (Burning sensation)	0-Absent 1-Occassionaly present 2-Frequently present 3-Continuously present throughout the day
9.	*Upadeha* (Stingy mucous discharge)	0-Absent 1-Occasionally present 2-Frequently present and able to open the eyes easily. 3- Frequently present and unable to open the eyes easily

Objective parameter: 1] chirmer's Test 2] Tear film break-up time were assisted.
Statistical analysis: Statistical analysis was done using SPSS VER. 20. Friedman's test is used to analyze the significance of change in Subjective parameters. Wilcoxon signed rank test is done for post Hoc with Bonferroni correction on parameters that show significance in Friedman's test, to interpret the time of significant change. For the objective parameter, Repeated Measures ANOVA was done to analyze the significant change. For the objective parameter, a Paired T test was also done to determine the significance at BT and AT.

RESULT
Among the registered patients, 28 patients had an aggravating factor as the environmental factor, while 3 of patients had routine work as an aggravating factor. (Figure 1) Among the registered patients, 7 patients got relieved by taking rest, 9 patients got relieved by taking medicine, 8 patients got relieved by washing with water, 3 patients got relief by sitting in a dark room, and 4 patients got relief by rubbing the eye. (Figure 2)

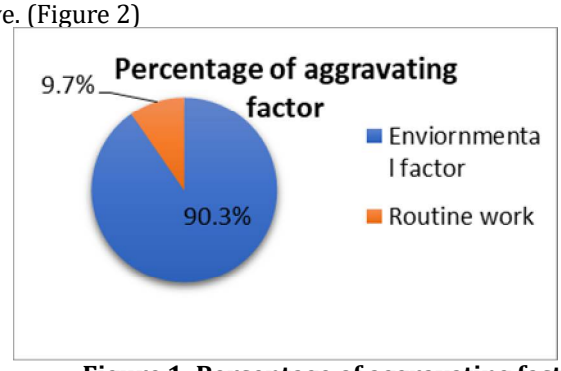


Figure 1: Percentage of aggravating factor

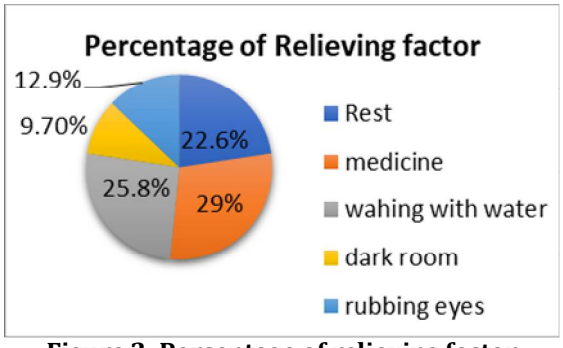
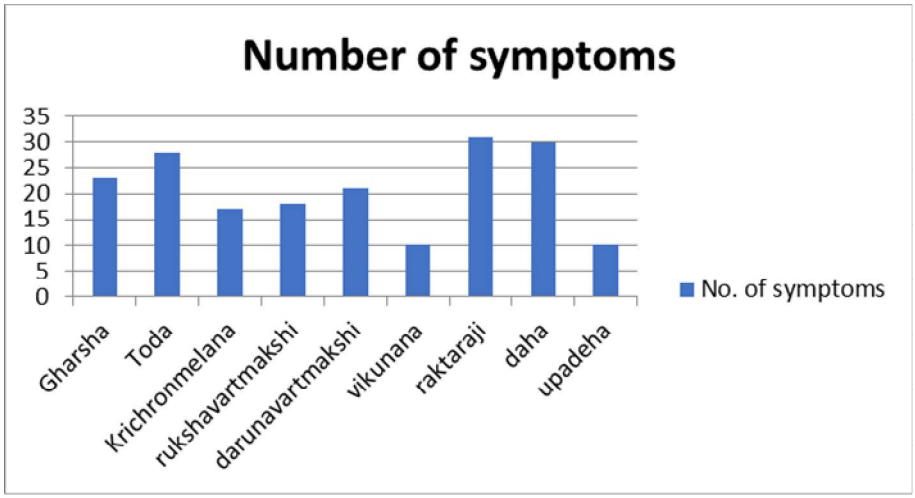


Figure 2: Percentage of relieving factor

The symptom-wise distribution of the patients was: Among the screened patients, 74.2 % of patients were having the symptom of *gharsha*, 90.3% of patients were having the symptom of *toda*, 54.8 % of patientswere having the symptom of *krichonmelana*, 58.1 % of patients were having the symptom of *rukshavartmakshi*,

67.7 % of patients were having the symptom of *daruna vartamakshi*, and 32.3 % were having the symptom of *vikunana*. 100 % of patients were having *rakta raji* as the symptom, 96.8% were having the symptom of *daha*, 16.1% were having the symptom of *upadeha*. (Graph 1)



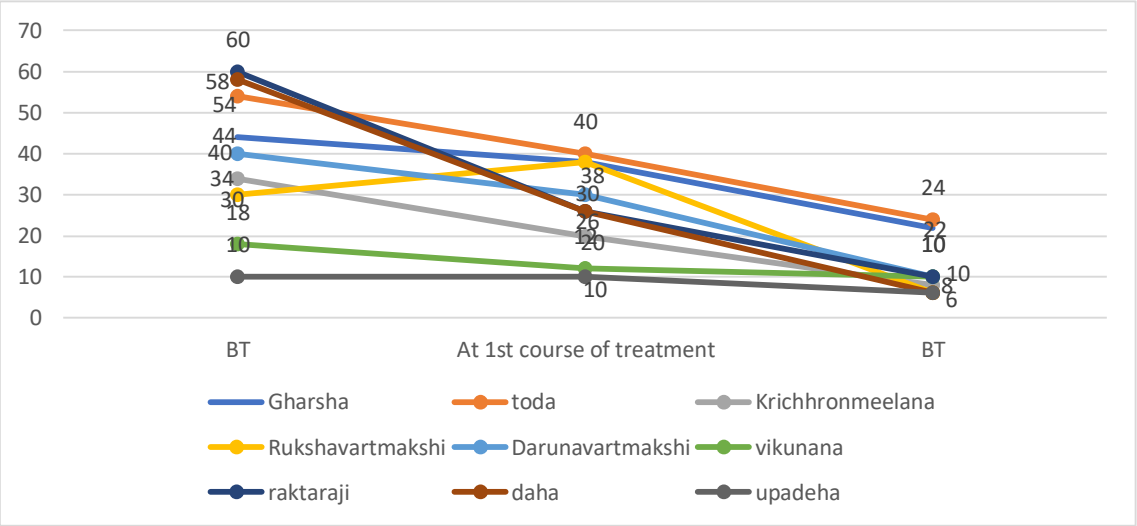
Graph 1: The symptom-wise distribution of the patients

The severity of symptoms was classified as nil, mild, moderate and severe. Each symptom was assessed accordingly. (Table 2)

Table 2: Severity of symptoms

Symptoms	Nil	%	Mild	%	Moderate	%	Severe	%
Gharsha	14	25.8	26	41.9	20	32.3	0	0
Toda	06	9.7	30	48.4	26	41.9	0	0
Krichronmelana	28	45.2	34	54.8	0	0	0	0
Ruksha-vartmakshi	26	41.9	30	48.4	6	9.7	0	0
Daruna- vartmakshi	20	32.3	34	54.8	8	12.9	0	0
Vikunana	42	67.7	20	32.3	0	0	0	0
Raktaraji	0	0	12	19.4	50	80.6	0	0
Daha	2	3.2	14	22.6	46	74.2	0	0
Upadeha	52	83.9	8	12.9	2	3.2	0	0

Out of 31 patients, one patient dropped out because of discontinuation of treatment. A total of 30 patients were analyzed statistically. (Each eye considered individually, i.e., 60 eyes). There was a reduction in all the symptoms during the time of treatment which is statically significant at the level of $p < 0.001$ which is indicated by the X^2 value (Friedman test). The study reveals that the number of eyes affected by different symptoms like *Gharsha, toda,* etc, before starting treatment, at the first course of treatment, and after treatment are represented in Graph 2.



Graph 2: Analysis of all the symptoms of Sushkaakshi at the different times of treatment

All the symptoms were assessed statistically by using Friedman's test and the Wilcoxon test. Friedman's test is used to analyze the significance of change in Subjective parameters. Wilcoxon signed rank test is done for post-Hoc with Bonferroni correction on parameters that show significance in Friedman's test, to interpret the time of significant change. According to statistical analysis, only the *Updeha* symptom shows a nonsignificant change having During first course of treatment (for 7 days), 15 days of first course of treatment, in 2nd course of treatment and in subsequent follow up there was no reduction in symptom noticed, as the p value is > 0.00714. *Raktraji, Daha, Toda, and Garsha* were the most observed symptoms, followed by *Krichronmeelana, Rukshavartmakshi, Darunavartmakshi, and Vikunana, which* were reduced significantly at the 1st course of treatment which is statistically significant at the level of p <0.001. After 15 days of the first course of treatment, in 2nd course of treatment, and in the first follow-up period, there were significant changes noticed in the subjects as the p-value is < 0.00714. During the 2nd, 3rd & 4th follow-up period, there was no significant change observed as the p-value>0.00714. The result of the objective parameters was analyzed by a paired t-test. (Table 3) There was a significant improvement in the value of ST as the mean value of ST (BT) is increased from 7.25mm to 9.73mm (AT) with a mean difference of -2.443 which is found to be statistically significant by paired T test. The mean value of ST is found to be increased from 7.25 to 11.15, including the follow-up by Repeated Measures ANOVA. (Table 4) In pair-wise comparison of ST at different levels, including follow-up, it is found to be statistically significant but not clinically significant (Normal value >15mm), and further reduction in Schimmer's value is not observed.

Table 3: Results on ST analyzed by paired T test.

ST	N	Mean	Mean diff	T-Value	Df	P-value
BT	60	7.25mm				
AT	60	9.73 mm	-2.483	-9.593	59	.0001

Repeated measures ANOVA was done for the parameters of ST to find out the time of significance where there is improvement in Schimmer's test, including the follow-up period.

Table 4: Effect of Schimmer's Test (Repeated Measures ANOVA)

			GREENHOUSE – GEISSER				Greenhouse – GeisserError df	
Parameter	N	Mean	Df	F value	P value	Size Effect		Remark
sch_BT 1 BE	60	7.25	4.592	36.859	.000	0.385	270.907	S
sch_At 1 BE		8.57						
Sch_BT 2 BE		8.70						
Sch AT 2 BE		9.73						
sch_FU1 BE		9.17						
sch_FU2 BE		9.70						
sch_FU3 BE		9.98						
sch_FU4 BE		11.15						

Table No. 4 shows the mean value of ST of 60 eyes at each level of study including follow-up, and it implies that the mean value of ST before treatment has been improved from 7.25 seconds to 11.15 seconds after the fourth follow-up at Greenhouse-Geisser Error df 270.907 with a size effect of 0.385, which is statistically significant at p-value <0.05. There was a significant improvement in the value of TBUT as the mean value of TBUT is found to be increased from 8.18sec to 11.35sec with a mean difference of -2.1 sec, which is found to be statistically significant by paired T test, including the follow-up by RM Anova. In pair-wise comparison of TBUT at different levels, including follow-up, it is found to be statistically as well as clinically significant, and further reduction in the value of TBUT is not observed.

Table 5: Result on TBUTPaired T-test

TBUT	N	Mean	Mean diff	Df	T-Value	P-value
BT	60	8.18 Sec	-2.1	59	-8.893	.0001
AT	60	10.28 Sec				

Table 6: Effect of Tear Film Break-up Time Test (Repeated Measures ANOVA)

			GREENHOUSE – GEISSER				Green house–Geisser Error df	
Parameter	N	Mean	Df	F value	P value	Size Effect		Remark
TBUT_BT 1 BE	60	8.18	5.456	22.171	.000	0.273	321.883	S
TBUT AT 1 BE		8.77						
TBUT_BT 2 BE		9.62						
TBUT_ AT 2 BE		10.28						
TBUT_FU1		9.57						
TBUT_FU2		9.77						
TBUT_FU3		10.62						
TBUT_FU4		11.35						

Table No. 6 shows the mean value of TBUT of 60 eyes at each level of study, including follow-up, and it implies that the mean value of TBUT before treatment has been improved from 8.18sec to 11.35sec after the fourth follow-up at Greenhouse-Geisser Error df 270.907 with a size effect of 0.385, which is statistically significant at p-value <0.05.

DISCUSSION

Signs of *Shuskakshipaka*, both ocular and non-ocular, strongly reflect *Vata* dominating *Pittaja* vitiation in the eyes and body overall. The distinctive feature of Ayurvedic ophthalmology is the topical technique for drug delivery known as *Kriyakalpas* or topical ocular therapies, which comprises *Seka, Aschyotana, Pindi, Bidalaka*, *Tarpana*, and *Putapaka*. The most potent *Kriyakalpa* for *Netra vikara,* particularly in *niramavastha* (the later phases of the disease when acute symptoms occur), is *Tarpana.*[9] In *Chikitsa Manjari, tarapana* with *Yashtimadhu Ghruta* is stated in relation to *Vatapaittika Netra Roga*.[10] Thus, under *sarvagata roga, Sushkakshipaka* is a *vatapaittika sadhya vyadhi.* Ayurvedic scriptures extensively record the pharmacological qualities of *Ghrita* (ghee) and *Yashtimadhu* (*Glycyrrhiza glabra*). The anti-inflammatory, demulcent, and antioxidant qualities of *yashtimadhu* aid in the repair of the ocular surface and the stabilisation of the tear film. Nevertheless, *ghrita* is renowned for its nourishing (*snehana*) qualities,[11] which may aid in replenishing the ocular lubricant and lessening the dryness connected to DES. In addition, the *Tarpana* treatment is intended to offer targeted nutrition to the ocular tissues, facilitating lubrication and renewal.[12] By keeping medicated ghee on the eyes for an extended period of time, this unusual Ayurvedic procedure increases the duration of contact between the therapeutic agents and the ocular surface, which improves treatment effectiveness. The indications and symptoms of *Sushkakshipaka* were found to be reduced by *Yashtimadhu's madhurarasa*, *Snigdha guna, Sheetha veerya,* and *chakshushya* properties, and by *Ghrita's Snigdha, Brumhana, and Vatapittahara* characteristics.[13] *Ruksha guna* of *vata* increases in *netra*, resulting in *adravata* (*Shushkata*) of *netra* and the production of *Gharsha.* The *snigdha, brumhana,* and *vatahara* qualities of *yashtimadhu,* as well as the *vata pittahara, brumhana,* and *snigdha guna of ghrita*, impede the *gharsha* symptom. Because *Yashtimadhu* contains glycyrrhetinic acid and isoliquiritigenin, which have immune-stimulating properties, T-cells are prevented from releasing cytokines (mostly interleukin-6), which exacerbate the inflammatory aspect of dry eye syndrome. As a result, it aids in minimizing the foreign body sensation symptom. An increase in the *ruksha* and *khara guna* of *vata* causes the symptoms of *toda* (prickling pain) to manifest. One of the *vruddhi lakshana samanya vata*. Thus, by virtue of *yashtimadhu's snigdha, brumhana, vatahara,* and

vedanasthapaka properties as well as its *Tarpana* effect, *ghrita* aids in lessening the symptoms of *gharsha*. The illness or failure of the functional unit results in an unstable and poorly maintained tear film, which induces prickling pain and other symptoms of ocular irritation and may cause damage to the ocular surface epithelium. This is the cause of the pricking pain associated with dry eye syndrome.[14] Chemicals such as glycochalcones, glycyrrhetinic acid, and glabrene have anti-inflammatory and immunomodulatory properties[15] that may aid in reducing the epithelial defect caused by the inflammatory response over the ocular surface of dry eye illness. Thus, it aids in lessening the prickling sensation. Reduced tear production causes difficulty opening and closing the eyelids, and clearing the ocular surface triggers an inflammatory response, including soluble and cellular mediators that increase friction in the eyes during closure and opening.[16] *Krichronmeelana* (difficulty in opening and closing eyelids) is formed due to the combination of *Ruksha, Khara guna vruddhi,* and *chalagati* of *vata* and *netra*. As a result of the *guna karmukata*, particularly the *snigdha*, and *Tarpana kriyakalpa*, the *gunas* of *Yastimadhu Ghruta, Brumhana,* and *Preenana* aid in mitigating the symptoms of *Krichronmeelana*. *Raksh* and *Daruna Vartmakshi* are formed due to an increase in the *ruksha* and *khara guna* of *vata* and the *tikshna guna* of *pitta. Ruksha* and *Daruna Vartmakshi's* symptoms can be lessened by the *Yashtimadhu Ghrita's snigdha, brumhana, vata-pittahara,* and *rasayana* properties. When dry eye syndrome manifests as painful and dry eyelids, the cause is apoptosis, which happens as a result of inflammatory processes across the ocular surfaces. Photophobia is caused by reversible conjunctival squamous metaplasia and punctate epithelial erosions of the cornea and conjunctiva.[17] Glabridin, Isoliquiritigenin, and Licochalcones' antioxidant properties in *Yashtimadhu* aid in lowering the apoptosis on the ocular surface brought on by DES.[18] The increase in *ashraya-ashrayi bhava*, which leads to *rakta raji,* would cause an increase in *Ushna, Tikshna guna of pitta,* and *ragata of rakta.* The production of inflammatory cytokines and MMPs throughout the ocular surface is one of the inflammatory processes that are triggered by hyperosmolarity in the epithelial surface cells. Goblet cells and other surface epithelial cells undergo apoptosis as a result of these inflammatory events; consequently, the loss of goblet cells may be directly linked to the consequences of long-term inflammation. It ultimately leads to a lack of mucin in the tear film, which causes dry eyes. The meibomian glands and goblet cells have estrogen receptors.[19] The presence of phytoestrogens in Yashtimadhu, such as Glabridin, Isoliquiritigenin, and Glabrene, may aid in the formation of the tear film's lipid and mucin layers, maintaining the tear film's integrity and the moisture content of the ocular surfaces. Both the *laghu guna of vata dosha* and the *tikshna guna* of *pitta* will manifest as a result of the increase in *ushna*. The *yashtimadhu ghrita's Snigdha-Sheeta guna* aids in easing the symptoms of daha. *Yashtimadhu* contains glycyrrhetinic acid, licorice, and glazene, which function as anti-inflammatory agents by preventing the synthesis of inflammatory mediators such as cytokines, T-cell activators, matrix mettaloproteiase [20].

CONCLUSION

Sushkakshipaka can be correlated to Dry Eye Syndrome and treated well with Ayurveda. It is discovered that *Yashtimadhu Ghruta Tarpana* has a considerable beneficial effect on lowering the signs and symptoms of *Sushkakshipaka* during treatment. Nevertheless, because of its single-arm design and relatively limited sample size, more extensive randomised controlled trials would be required in the future to validate these findings and ascertain the long-term benefits of *Yashtimadhu Ghrita Tarpana*.

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