



A Comparative Clinical Trial on the Sustained Effect of Topical Application of Durva Ghritam against Artificial Tear Drops/Eye Ointments in Dry Eye-A Retrospective Study

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Abstract:

Aim: To evaluate the sustained effect of ayurvedic treatment in comparison with artificial teardrops/eye ointments in the management of dry eye.

Method: 20 patients who approached the OPD of department of Salakyatantra, Govt. Ayurveda college, Tripunithura for an alternate option for the management of dry eye and had undertaken allopathic management for a period of 6 months or more were selected. They were graded according to symptoms and were given durva ghrita (medicated ghee) aschyotana (topical application) for three months. The symptoms were compared after a follow up period of three months and was statistically evaluated using Friedman's Rank test

Result: The patients even with severe symptoms showed almost complete relief with and didn't show any symptoms in follow up period when they used durva ghritam. But the same group when they used artificial tear/ointments showed only temporary relief of symptoms during drug usage and when stopped the drug, the symptoms recurred.

Conclusion: Durva ghritam provides sustained effect in a more economical way than artificial tear drops.

Keywords: dry eyes, durva ghritam, artificial tear drops.

1. INTRODUCTION

The dry eye syndrome is among the most common ocular surface disorder worldwide with prevalence varying from 5%-35% while in India it is 29.25%¹. It can be sjogren's or non-sjogren's type. The dry eye syndrome can cause ocular discomfort by symptoms like grittiness, burning sensation, pricking pain of eye lids, photophobia². This disease is characterized by deterioration of corneal epithelium with punctate epithelial erosions. Their conjunctival epithelium will have squamous metaplasia with decreased goblet cells³.

Ayurvedic classics provide scientific explanations about dry eye under two headings, the mild to moderate dry eye with difficulty in opening eyes, heaviness and pain of eyelids in morning, gritty sensation as krichronmeela⁴, and the severe dry eye with additional symptoms of dryness like severe photophobia, burning sensation associated with erosions of conjunctiva and corneal is termed as suskakshipaka⁵

According to allopathic system, dry eye is not generally curable and the management is structured around the control of symptoms and prevention of complication⁶. Hence the artificial tears, the usual therapy for dry eye has been designed with the physical properties of tear film having hydrophilic polymers which help in wetting and lubricating ocular surface thus controlling the symptoms during usage period. But an ideal tear supplement should help in the maintenance of normal ocular surface and aid in repair of damaged epithelial cells along with lubrication of ocular surface⁷. Now the modern ophthalmic researchers are concentrating on eye drops having cell repairing property with options ranging from sodium hyaluronidase to autologous serum as topical application

But Ayurveda considers krichronmeela and suskakshipaka as curable diseases. Ayurvedic combination, durvaghritam though, not physically similar to tear film like the artificial tears but have lubricating effect and cell repair action and can provide sustained relief of dry eye symptoms.

Durvaghrita is a traditional ayurvedic combination used by reputed vaidyas (traditional ayurvedic doctors) of Kerala for healing ocular trauma because of its cell repairing property⁸. Our pilot studies have proved that durvaghrita can provide long lasting effect in dry eye

Non co-operation of allopathic hospitals in conducting RCT (Randomized controlled clinical trial) in addition to the ethical problem in providing allopathic medicine in an ayurvedic centre forced us to compare the result retrospectively.

2. PATIENTS AND METHODS

2.1. Study Population

20 patients (13 females and 7 males) who had dry eye (mild, moderate or severe) were enrolled into the study by using consecutive sampling technique. The patients were selected based on the following inclusion criteria a) history of dry eye for 6months or more b) undertaken allopathic management (artificial tear/eye ointments) for dry eye symptoms c)having the classical symptoms of dry eye.

Out of the 20 patients,10 were mild cases, 3 moderate cases and 6 were severe cases of dry eye. The mild and moderate varieties can be correlated with krichronmeela¹ and severe variety with suskakshipaka¹. The patients were advised to use 1 drop durvaghritam at night (mild and moderate cases) and 1 drop twice daily (severe cases) for three months with hospital visits in first and third month and a visit after 3 months of follow up period. The patients whose symptoms relieved before 3 months were advised to discontinue the use of medication and were followed.

2.2. Study Design

A comparative clinical trial has been conducted at Government Ayurveda college Hospital Tripunithura with approval from local ethical committee. A questionnaire was prepared to collect the data retrospectively to assess the sustained effect of allopathic management and further intervened by ayurvedic medication and followed prospectively to collect and compare the data. As all the patients have under taken allopathic treatment for 6 months or more, the grading at first visit is considered as the total outcome of allopathic management. The study was done over 18 months.

2.3. Tests Performed

Though there are many diagnostic tests available for dry eye, lack of repeatability and poor co-relation of symptoms with the test, the diagnosis can mainly be made from clinical signs and symptoms¹⁰. Hence only subjective symptoms were considered in this study. The patients were examined at a) first visit b) after 1 month of treatment c) after 3 months of treatment d) 3 months after treatment. Grading was done according to VAS scale. Grade 1-4 constitute mild symptoms, 5-7 constitute moderate and 8-10 severe.

2.4. Study Material

Durvaghrita a classical Kerala Ayurveda preparation was prepared according to snehapakavidhi (unctuous preparation). The juice of durva (*Cynodondactylon*), the paste of yashtimadhu (*Glycirrhisaglabra*), milk and ghee are its constituents⁹. The drugs used to prepare durvaghritam are having the properties like madhurasam (sweet taste), madhuravipakam (sweet after digestion), seethavirya (cold potency) and vatapithasamana (relieves vata and pitha). Also the constituents are snigdham (act as lubricant), ropanam (healing property), jeevaneeyam (promote cell health) and rasayanam (rejuvenating property). Suskakshipaka being vatapitha predominant disease and krichronmeela being vatapredominant¹⁰ the formulation will be very much efficient in managing these two conditions. The snigda (slimy), madhura (sweet) and sita (cold) gunas (properties) helps in maintaining the stability of tear film by reducing the evaporation of tear film and the ropana (healing) guna (property) helps in corneal and conjunctival repair with the jeevaneeya and rasayanagunas helping in revitalizing lachrymal glands thus maintaining the sustained effect.

Being constituted with milk and ghee which are amphiphilic molecules, durvaghrita helps to strengthen the lipid layer of tear film there by reducing the evaporation of tear film. The wound

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healing property of the drug⁷ helps in the repair of corneal and conjunctival epithelium; and the antioxidant and healing properties helps in revitalizing the lachrymal gland thus maintaining a sustained effect which is not possible with the artificial tears.

Table1. Showing the proportion of ingredients in Durva ghrita

Contents	Latin/English name	Proportion
Durva(swarasa)	<i>Cynodondactylon Linn</i>	3.072l
Yashtimadhu (kalka)	<i>Glycyrrhizaglabra Linn</i>	64g
Goghrita	cow's ghee	768g
Godugda	cow's milk	768ml

3. RESULT

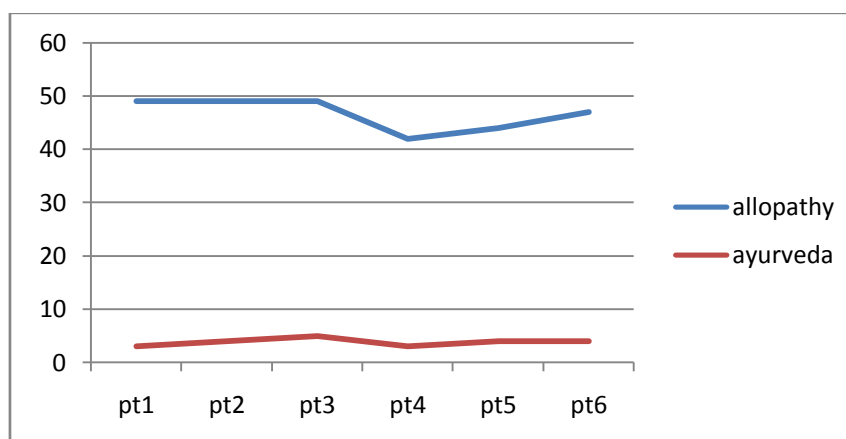
Statistical analysis was done using Friedmann's rank test. The study showed that the severe cases registered 67.2% relief of symptoms with 1 month of drug usage and 91.1% relief with 3 months of usage while after 3 months follow up the relief was 91.8%. For moderate cases the improvement was 56.7% after second visit and 91.2% after third visit which was retained during follow up period, while mild cases achieved 87.72% relief by 1 month usage and 99.5% after 3 months with the same % relief after the follow up.

Considering symptom wise comparison the easily relieving symptoms in ascending order are burning sensation ($\chi^2=18.03, p<.001$), photophobia ($\chi^2=27.06, p<.001$), difficulty in opening eyes ($\chi^2=63.3, p<.001$), pricking pain ($\chi^2=110.16, p<.001$), grittiness ($\chi^2=265.5, p<.001$).

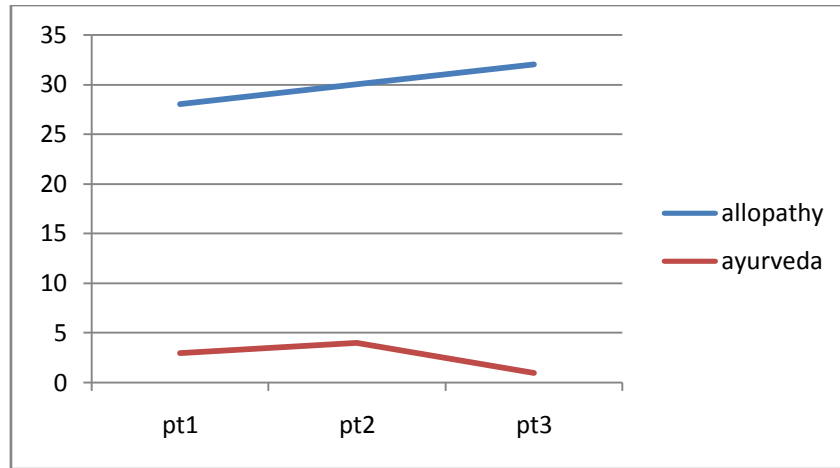
Table2. Showing allopathic medicine used before ayurvedic treatment by severe cases

Patient no & age	Duration of disease	Medicines used	frequency	duration	Reappearance of symptoms on medicine stoppage
Patient 1, 55 yrs	8 yrs	Refresh gel e/d Refresh ointment Lacrigel ointment	Every 5 minutes	1 year	With in half an hour
.Patient 2, 58 yrs	6 yrs	Velgel e/d Panthe gel	Every 30 minutes	2 years	With in 1 hour
Patient 3, 65 yrs	4 yrs	Refresh gel e/d Refresh ointment	Every 2 hours	18 months	With in 4 hours
Patient 4, 68 yrs	5 yrs	Genteal e/d, Genteal gel	Every 15 min	2 years	With in 1 hour
Patient 5, 23 yrs	6 yrs	Refresh gel e/d Panthe gel ointment ISOL-6 ointment	Every 15 minutes	6 months	With in 2 hours
Patient 6, 40 yrs	3 yrs	Genteal e/d ,genteal gel	Every 2 hrs	1 year	With in half day

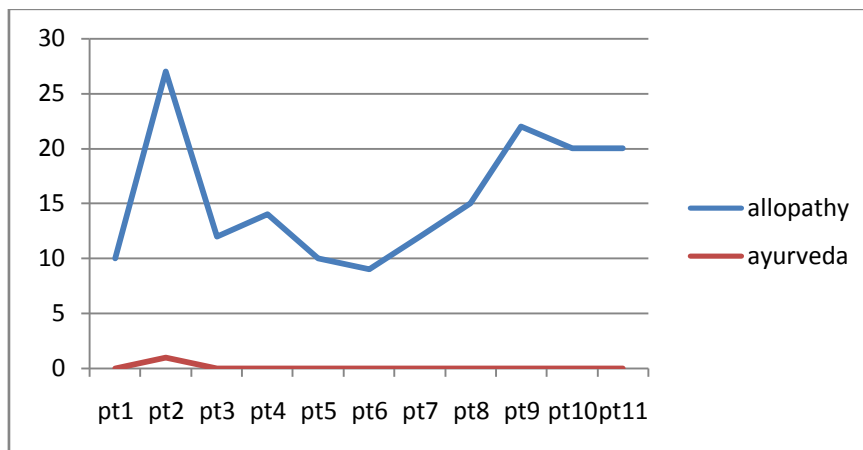
Graphs 1-3 showing total score of symptoms after allopathic and ayurvedic treatments



Graph1. Severe cases

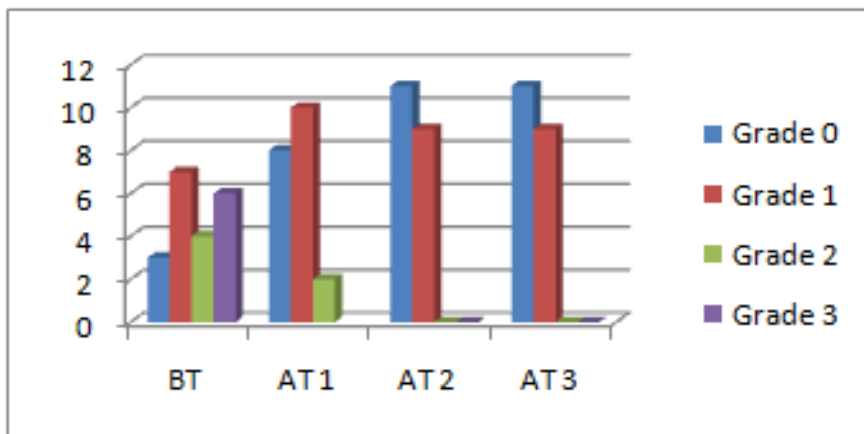


Graph2. Moderate cases



Graph3. Mild cases

Graphs a-e showing status of each symptom before and after ayurvedic treatment



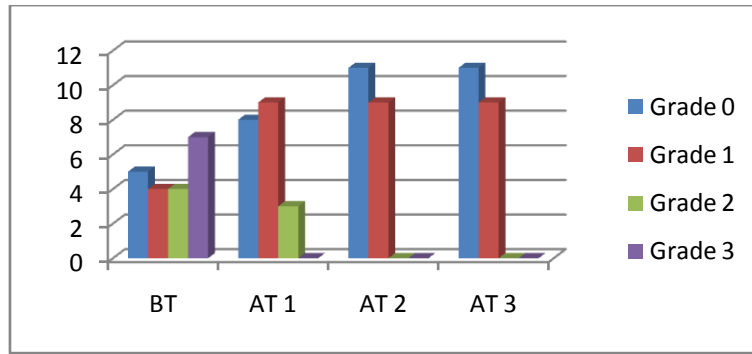
BT –Before Treatment

AT 1-After 1 month treatment

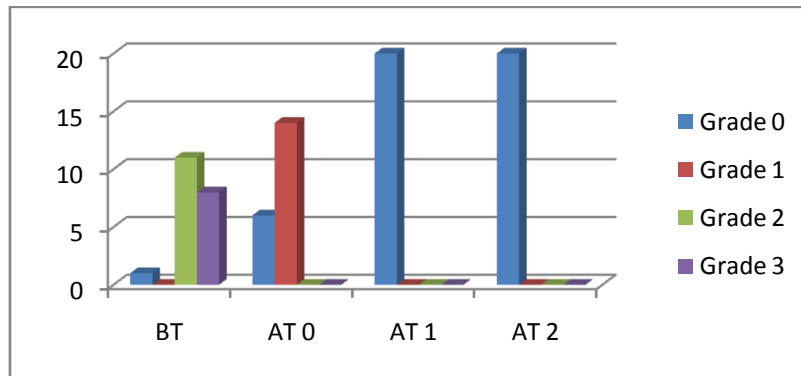
AT 2-After 3 months treatment

AT 3-After 3 months of follow up

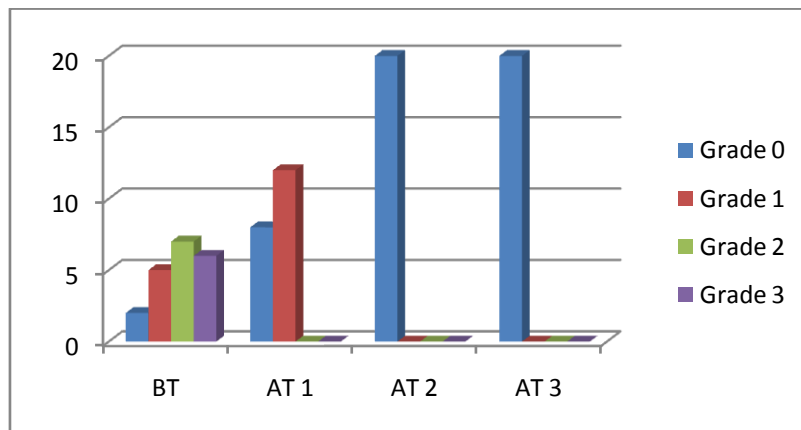
GraphA. Photophobia



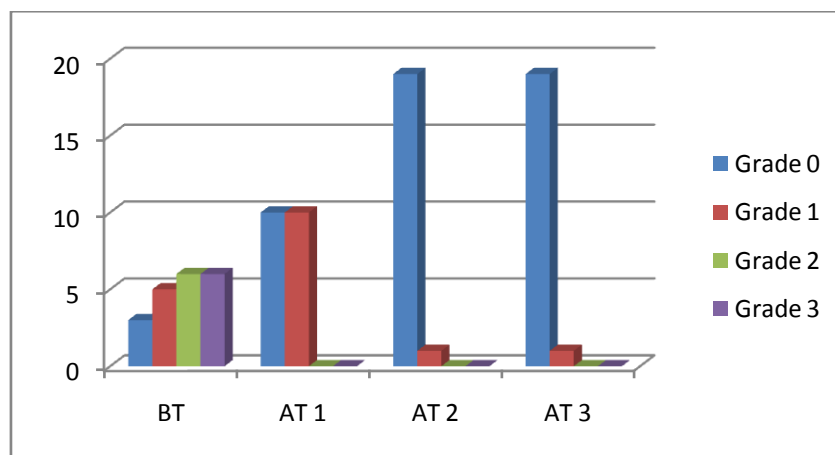
GraphB. *Difficulty to open eyes*



GraphC. *Grittiness*



GraphD. *Pricking pain*



GraphE. *Burning sensation*

4. DISCUSSION

From the results it is seen that the durva ghrita can provide sustained relief in non sjogren'skcs (kerato conjunctivitis sicca) which cannot be provided by artificial tear and that too in a very economical way. Considering symptom wise, grittiness and pricking pain are the most easily relieved symptoms with patients getting 100% relief after treatment period where as 95% relief was obtained for burning sensation and 55% relief was obtained for both photophobia and difficulty to open eyes which all were retained during follow up period also.

Durvaghrita has a lipid base which being amphiphilic, gets bound to the tear film thus reducing its evaporation. This action can be provided by all ghee based eye formulation. But the cure of dry eye occurs only if the medicine can reduce the ocular surface inflammation and repair the damaged cells in lacrymalglands. Being a proven drug in ocular surface wounds, durvaghritam reduces inflammation and aids in repairing damaged lachrymal cells thus providing a sustained effect. Also the antioxidant properties of milk and ghee revitalize the lachrymal gland.

The healing effect of durva ghrita is due the constituent drugs. Thedurva,yashti,milk and ghee are all traditional wound healers with anti-inflammatory properties.

As the modern medicine is searching for options in managing this highly prevalent condition with treatments ranging from artificial tears to autologous serum traditional medicine can provide an answer to this much sought question.

Considering the economic aspects 10 ml of refresh tear costs INR(Indian Rupees)135 whereas the same amount of durvaghritamcosts about INR 20.With this much cost,the change durvaghritam bringing into the quality of life of dry eye patients is satisfying.

The study has its own set of lacunas. A randomized controlled clinical study involving ayurvedic and allopathic treatment groups would have given better scopes for comparison, but is possible only with the co-operation of allopathic ophthalmologists. Also the study if conducted in a larger centre with more no of patients and involving techniques like impression cytology would have a larger impact.

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