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PROTOCOL OF EVALUATION OF THE EFFICACY OF *MUDGAPARNI GHRIT AASCHYOTANA* IN THE MANAGEMENT OF *SHUSHKAKSHIPAKA* (DRY EYE SYNDROME)

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ABSTRACT

Patients with recurrent dry eyes are increasingly reporting that their modern way of life exposes them to high levels of radiation, whether from VDTs (Video display terminals), computers, televisions, compact fluorescent lamps, mobile phones, or any other source. Dry eye syndrome has been treated with lubricating medicine (eye drops) for a long time in modern Ayurveda. As a result, Dry eye syndrome will be treated with Mudgaparni Ghrita Aaschotana. Objectives Comparison of Mudgaparni Aaschyotana with Glycerin Eye Drops on Shushakakshipaka is the purpose of this study (dry eyes). Clinical observational study is the method of choice for this research. Patients with dry eye syndrome will be divided into two groups, with 51 patients in Group I and the other 51 in Group II. CMC 0.5 percent with glycerin eye drops will be administered to 51 patients in Group II. Results The results will be based on research involving post-treatment observation. Conclusion: the conclusion that can be drawn as a result of what has been observed and discovered.

KEYWORDS: Dry eye, Mudgaparni, Aaschyotana, Dry eye.

INTRODUCTION

It has been said that eyes are the most valuable possession and life is colorless without them. It has been very well said in Ayurvedas text “those who wish to a live long-life; they must take the precaution of their eyes because, for a blind, day and night are the same ones. To provide sustained moisture & lubrication to maintain vision &itswell-being & depends upon the flow of tears. Composition of tears 1) water (for clean& moist), 2) oils (prevent evaporation of tears & act as a lubricant), 3) Mucus (help bind the tear layer). Tears also include natural antibiotics known as Lysozymes, which help to maintain the eye's surface healthy by battling germs and viruses. Abnormalities of any of the components of the secretion (qualitatively or quantitatively) lead to instability in this system, resulting in drying of the ocular surface and syndrome. Many conditions cause dryness of the eyes, hypofunction of lacrimal glands, mucin deficiency (eg. Vit. A deficiency), conjunctival scarring, excessive computer use, low humidity environment, contact lens users, etc. Dry eyes are more common in Metro-cities. Dry eye syndrome is far more likely to occur in places with high levels of air pollution than in cities with cleaner air, according to research. Dry Eye is a widespread disease accompanied by discomfort and potential risk of visual impairment. Dry eye is a multifactorial condition that can be caused by a number of factors, High risk in person who spends more than 8 hours using the computer. More than 75% of people who routinely use Computers at work may suffer from Dry eyes. Approximately 8% of the world population is suffering from the dry eye of which 78% are women. Dry eye might affect anywhere from 3.5 percent to 55 percent of people. According to studies conducted in the United States, more than 3.2 million females and 1.6 million males over the age of 50 suffer from moderate to severe Dry Eye.

Dry eye is defined by the National Eye Institute as "a tear film condition caused by tear deficit or excessive tear evaporation that causes damage to the interpalpebral ocular irritation. "Though Dry eye has no direct reference in Ayurvedic classics, however, an Ayurvedic approach can be given based on the fundamentals of Ayurveda. Conditions like;

Atishushaknetra, Assigner are mentioned in Nibhandhasamgrah Dalhan (commentaries on Sushrut Samhita). Shushkakshipak is mentioned in the classical literature of Ayurveda under Sarvagat Netraroga. Kaph is responsible for snigdhtwa (oiliness), sthiratwa (structural & functional integrity of body) utilizing it’s qualities like gurutwa & shitatwa. Tarpakkapha one of the five varieties of Kaph situated in siras is responsible for the integrity of sense organs. (Akshtarpanat Tarpak:) The collective function of tear film components can be correlated with the function of the Tarpakkaph. Lakshnas of Dry eye can be correlated with Shushkakshipak as per Ashatang Hridaya. The Nidan and samprapti of Shuskakshipak are same as that of Samanyanidan and Samprapti of Netraroga. The doshas get vitiated due to individual dosh dushti karan. Among them, those causes are Achakshushya and Pitta prakopaka move upwards through the Siras and get located in netras various diseases in Vartmamandala, Sandhi, Shukla mandala, Krushnamandala. At present, there is no permanent treatment for Dry EyeSyndrome and there is a weak correlation between signs and symptoms. The uncertain etiology and mechanisms of the disease'ssigns of progress make the management difficult. Therefore, it has a high and frequent recurrence. Based on what we know now, it's more appropriate to think of it as an ocular surface inflammatory condition rather than just a tear film insufficiency. So, to find out the better management and to establish the correlation of this disease with the disease having maximum similarity i.e. Shushkakshipak in Ayurvedic ophthalmology, the study had been carried out.

PREVIOUS WORK DONE

1) Dr. Sunil Anantarao Walewadikar the Therapeutic Efficacy of Erand Tail and Saindhav Jal Eye drops in dry eye (Maharashtra University of Health Sciences 2010-11)
2) Dr. Arunkumar Bapurao Biradar to study the role of Goghritamanda Aaschyotana in shushkakshipaka w.s.r. dry eye syndrome.
3) Dr. Aboli Mujawar An open Controlled Clinical Study of Yashtimadhu Grita Aaschyotanain Shushkakshipaka with special reference to Dry Eye Syndrome 2012-13.
4) The purpose of this research is to see how effective of Jeevanteesiddha ghrita tarpan in shushkakshipaka (dry eye syndrome) w.s.r to dry eye syndrome.
5) The purpose of this research is to see how effective of Triphala ghrita in Shushkakshipaka with special reference to dry eye syndrome (Muhs Nashik 2012-13).
6) The purpose of this research is to see how effective of Triphala ghrita tarpan in management Shushkakshipak w.s.r to dry eye syndrome RGUHS Banglore 2010 by Dr. Gangadhar Thimmapur. Hassan Karnataka, RGUHS.

AIMS AND OBJECTIVES

Aims

Evaluation of the efficacy of *Mudgaparni ghrit Aaschyotana* in the management of *Shushkakshipaka* (dry eye syndrome).

Objectives

Primary Objective

To compare the efficacy of Mudgaparni ghrit Aaschyotana with CMC 0.5% with glycerin eye drops on shushakakshipaka (dry eyes).

Secondary Objective

1) To study the causes of Dry eyes.
2) To assess the Mudgaparni ghrit Aaschyotana with CMC 0.5% with glycerin eye drop in the management of Shushkakshipak (Dry Eye).

Primary Hypothesis

There is statistically significant difference In Mudgaparni ghrit Aaschyotana than CMC eye drops in Shushkakshipaka (Dry eye syndrome).

Null Hypothesis

There is no difference in Mudgaparni ghrit Aaschyotana than CMC eye drop in Shushkakshipaka (Dry Eye syndrome).

MATERIAL & METHOD

Sampling procedure

Groups	No. of Patients	Age	Sex	Interventation	Dose	Duration	Route	Follow up
Group A study Group	51	18 yrs to 60 yrs	Male & Female	Mudagaparni Ghrit Aaschyotana	10 drop (200 vanghmatra)	15 Days	Local	15, 30, 45, 90 days
Group B Control Group	51	18 yrs to 60 yrs	Male & Female	CMC 0.05% with glycerine eye Drop	1 drop QID	15 days	Local	15, 30, 45, 90 days

Intervention

Group A: Mudgaparni ghrit Aaschyotana

Group B: CMC Eye Drop

METHODOLOGY

Type of Study-: Randomized standard control single blind superiority clinical Trial.

Sampling Procedure: Random sampling method.

Methods of data collection relevant to an objective

A. Clinical examination: All of the classic Shushkakshipak symptoms and signs will be documented in a comprehensive case report. Clinical examination will also include the dushti lakshanas of Doshas, Dushya, Dhatu, Agni, and prakruti, etc. Ophthalmologists will conduct an auto refract meter and ophthalmoscopy examination, and the Schirmer Test 1st and TBUT Tests will be recorded.

B. Literary source: In-depth research into relevant medical literature, such as Ayurvedic texts, Nighantus, and modern pharmacology textbooks. There are numerous books, periodicals, and papers published in e-journals that will be used to gather information.

Patients of Shushkakshipak (Dry Eye) will be selected from OPD and IPD of Datta Meghe Ayurvedic Medical College and Hospital and Research center (MGACH & RC), Salod (H) Wardha, Sawangi (Meghe).

Intervention

Group A: Mudgaparni ghrit Aaschyotana

Group B: CMC 0.5% with glycerin Eye Drop

Post objective parameters will be measured.

Excluded from analysis

Analyzed (n=51 in each group)

Post GTVRKS scoring will be performed

Sample Size

$n1= \kappa n2$,

$n2=(z\alpha + z\beta)2\ \sigma\ 2\ (1+1/\kappa)/\ (\mu E-\mu C-\ \delta)\ 2$

where $\kappa=n1n2/$ demonstrates treatment allocations, $z\beta$ is the upper βth-quantile and $z\alpha 2/$ is the upper $\alpha 2$th-quantile of the standard normal distribution.

μE is the true mean response of the experimental treatment;

μC is the true mean response of the control treatment;

δ>0 is the clinically meaningful difference

Fixed Scenario Elements	
Distribution	Normal
Method	Exact
Number of Sides	U
Alpha	0.05
Mean Difference	0.81

Standard	0.4
Deviation	
Group 1 Weight	1
Group 2 Weight	1
Nominal Power	0.8

Computed N Total	
Actual Power	**N Total**
0.851	92

Considering 10% dropout rate, Hence for one-sided hypothesis testing with the type, I error level set to 5%, a total of 102 patients – 51 patients in each group – would be required to detect a clinically meaningful difference of 20% with 80% power and the variance $\sigma 2=0.4$.

Reference: To evaluate the efficacy of Gritakumari (Aloe Vera Gel) in the management of Shushkakshipaka (Dry Eye Syndrome)

Population

Patients of Shushkakshipak (Dry Eye) will be selected from OPD and IPD of Datta Meghe Ayurvedic Medical College and Hospital and Research center (MGACH & RC), Salod (H) Wardha, Sawangi (Meghe).

Data collection tools and process

As long as a patient meets all of the study's eligibility requirements and is willing to sign a written consent form, they'll participate in this study.

Inclusion Criteria

1. Patients of all occupations.
2. Patients between 18-60 years of age are selected.
3. Patients are irrespective of age, sex, religion, and socioeconomic status.
4. Patients with Signs and Symptoms of mild Dry eye according to dry eye level gradation.
5. Tear film break-up timeless than 10sec.
6. Schirmer, I test positive less than 10 mm.

Exclusion Criteria

1. Patients with other infections of eyes like Corneal ulcers.
2. The patient recently operated on the eye.
3. Patients under medication like Chemotherapy, diuretics, antidepressants, or antipsychotic medications.
4. Patients having bleeding tendency.
5. Patients suffering from Trichiasis, dropping of the eyelid.
6. Patients who are not willing for trial.

Withdrawal

Patients will be withdrawn from the study on the following grounds:-

1. Patients will have the option to withdraw their names from the study at any time for any reason.
2. Failure of the patient to adhere to the protocol requirement.

3. Any adverse event occurs.
4. Those who are not responding to treatment and required another Drug intervention.

Treatment Schedule & Methodology

102 patients of dry eye were randomly selected and equally divided into 2 groups

Groups	No. of Patients	Age	Sex	Interventation	Dose	Duration	Route	Follow up
Group A study Group	51	18 yrs to 60 yrs	Male & Female	Mudagaparni Ghrit Aaschyotana	10 drop(200 vanghmatra)	15 Days	Local	15, 30, 45, 90 days
Group B Control Group	51	18 yrs to 60 yrs	Male & Female	CMC 0.05% with glycerine eye Drop	1 drop QID	15 days	Local	15, 30, 45, 90 days

Methods of preparation of mudgaparni ghrit

1) Mudgaparni kalka 1 pala (40 gm)
2) Mudgaparni kwatha- 64 Tola (640ml)
3) Goghrit 1/2Prastha(320gm)

All of the following components, along with the stirrer, are placed in utensils and placed on a gas stove or burner. Heat until “Snehasiddhi lakshana” appears in the combination of 320 ml of ghrit left in the utensils.

Assessment criteria

The assessment will be done based on the following subjective and objective Parameters.

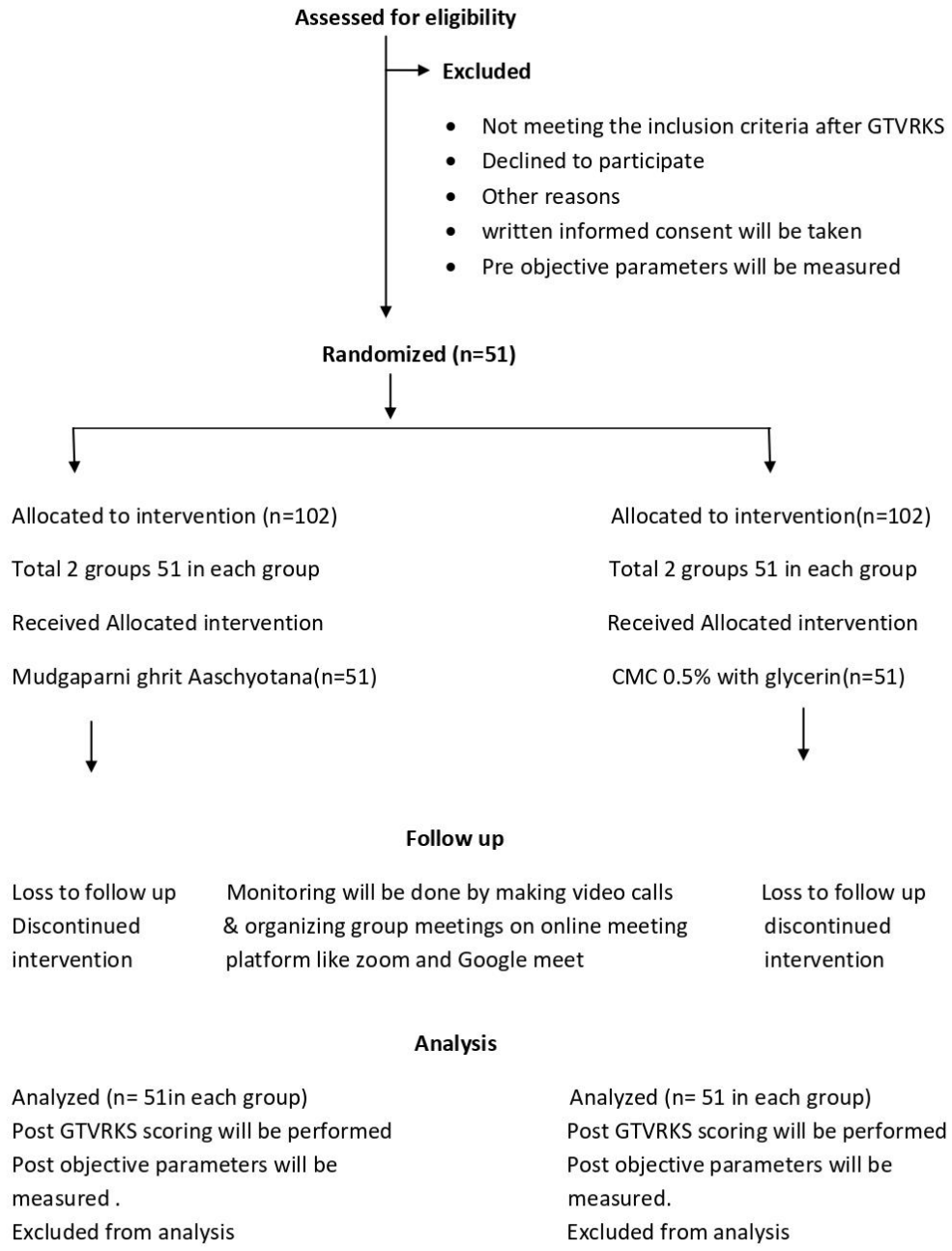
Grading of subjective parameters 14

	Never	Mild	Moderate	Severe Constantly
Gharsha (friction)\feeling of dirt in eye)	0	1	2	3
Toda (pricking pain)	0	1	2	3
Ruksha Daruna Vartmakshi (Dry painful lid of the eye)	0	1	2	3
Krichron meelan (Difficulty in opening and closing of eyelids)	0	1	2	3
Shushkata (dry eye)	0	1	2	3
Kandu (itching)	0	1	2	3
Vikoonanm (photophobia**)**	0	1	2	3

Grading of objective parameter 15

DRY EYE SEVERITY LEVEL	1	2	3	4
SCHIRMER TEST 1st(mm\5min)	Variable	<10	<5	<2
TFBU	Variable	<10	<5	<2

Study Design (flow chart): Active control single blind superiority clinical trial.



SAMPLE SIZE FORMULA WITH DESIRED ERROR OF MARGIN

Cochran Sample size formula with desired error of margin

Formula for calculating a sample for proportion

For populations that are large, Cochran (1963:75) developed the equation 1 to yield a representative sample for proportion

Equation 1: $n_0 = Z^2 pq / e^2$

Where;

$Z_{\alpha/2}$ is the level of significance at 5% i.e. 95% confidence interval = 1.96

p = Proportion of participants shows complete remission = 34% = 0.34

d = Error of margin = 10% = 0.10

$$n = \frac{1.96^2 * 0.34 * (1-0.34)}{0.10^2}$$

= 86.20 = 90 participants needed in the study

Study Reference: Ashwini BN et al

Formula Reference: Cochran, W. G. (1977). Sampling techniques (3rd ed.). New York: John Wiley & Sons.

Power of the test: 80%

Level of significance: 5%

Methods for justification

Justification for the figure is shown in the following image

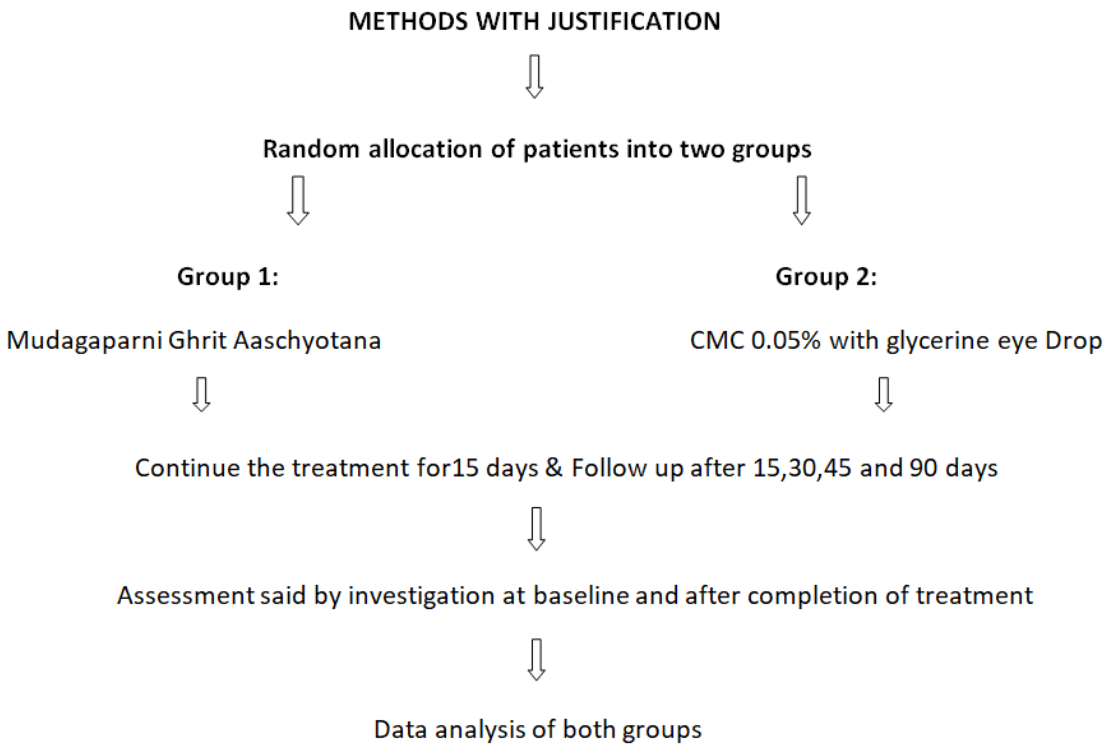


Fig: Data collection, management, and analysis methods.

TECHNIQUE OF DATA COLLECTION

For the study, only patients with Shushkakshipaka (Dry eye) were included and excluded. To get a complete picture of a patient's medical history, a thorough eye exam was conducted, including an assessment of their visual acuity. Patients were examined every fifteen days or sooner if their symptoms of Shushkakshipaka (Dry eye) warranted it. There are procedures in place for referring patients to higher centres if they do not respond to treatment within the allotted time frame or develop complications during treatment. Patients like these were not included in the research. Patients with Shushkakshipaka (Dry eye) were thoroughly examined with a slit lamp after their healing was complete, and any complications that occurred (such as redness, eye strain, or headache) were documented.

Data collection methods

Form designed to collect the Data.

Plans to promote participant: Pamphlets promoting the benefits of the treatment will be distributed to raise awareness. Dissemination of flyers in public areas such as eye clinics and government hospitals as well as bus and train stations and banks and schools.

Statistical methods

An appropriate statistical analysis will be performed, and a new patient will be assigned to replace a dropout.

Ethics and dissemination

Approval by a research ethics committee or institutional review board (REC/IRB) is on the agenda for this study.

Protocol amendments

Standard procedure of Mudgaparni ghrita aaschyotana topically.

Consent or assent

On the consent form, PI will secure the necessary permissions from the patient. There will be no leaks of private information.

Declaration of interests: None

Access to data: On Demand will be provided

Ancillary and post-trial care: If a patient is injured during the course of the trial, modern scientific treatment will be administered as soon as possible.

Dissemination policy: Registered Shushkashipaka patients will be collected from the specialty camp after they have been healed.

Expected Results: The end result will be based on careful observation and documentation.

DISCUSSION

Choosing this topic as a research project was motivated by the goal of providing relief through Ayurveda. Chaksusya or netrahita property, according to Bhavprakash and Raj, is the case with Nighantuvibhitak. Mudgaparni Ghrita is an ingredient in the therapeutic medicine. According to Ayurveda fundamental, dry eye syndrome may consider as vata-pitta pradhanvyadhi. Mudgaparni pacifies pitta due to madhura and sheeta Madhura it has Chakshushya (Improve vision good for eyes) Shothaghna (Relives swelling, oedema, anti-inflammatory properties which relievs symptoms of Shushkakshipaka (Dry eye).Ghrita has a positive effect on the eye. You can use this to alleviate eye dryness and burning sensation because of its tridoshaghna properties.

Key results – Mudgaparni ghrita is the best treatment for eye dryness, according to researchers.

Intermittent recording of the conditions in CRF will be used to record observations made during treatment and during the 90-day follow-up period. Before treatment (D0) and after treatment 15th, 30th, 45th, 90th.

CONCLUSION: On the basis of results, the conclusion will be drowned.

REFERENCES

1. Charaksamhita: with commentary by Chakrapani as AyurvedDipika 2006, Edited by Vaidya Yadavaji Trikamaji published by Choukhamba sanskritpratishthan Varanasi.
2. Sushrutsamhita: Ayurvedtatvsandeepika Edited by kaviraj Ambikadattashastri published by Choukhamba sanskritpratishthan Varanasi.
3. Ashtanghridayam: By Arundatta Sarvangsundar edited by Dr. Brahmanand Tripathi published by Choukhamba sanskritpratishthan Varanasi.
4. Ashtangasangraha with Shashilekha commentary Edited by Dr. Shriprasad Sharma published by Choukhamba sanskritpratishthan Varanasi.
5. Madhavnidan Uttarardha Madhukosh Vidyotini edited by Aayurvedacharya Shri Sudarshanshastri published by Choukhamba sanskritpratishthan Varanasi.
6. Sharangdharsamhita edited by Brahmadatta Tripathi 19th Edition, 2007, Choukhamba Oriental a Varanasi.
7. Bhavprakhash: of Bhavamishra edited by Pandit Shri Brahma Shankar Mishra published by Choukhamba Sanskrit bhavan Varanasi.
8. Haritsamhita edited by Pandit Hariprasad Tripathi published by Choukhamba Sanskrit bhavan Varanasi.
9. Yogaratnakar: Edited by Bhishakratna Shri Laxmipati Shastri published by Choukhamba Sanskrit bhavan Varanasi
10. Bhavprakashnighantu Edited Dr. Indradev Tripathi published by Choukhamba Sanskrit bhavan Varanasi. 137.
11. Kaidev nighantu.
12. Dravyagun Vidnyan: Edited by Dr.J.L.N.Shastry published by Choukhamba Sanskrit bhavan Varanasi.
13. Chakradatta savimarsha Vaidyaprabha edited by Dr.Indradev Tripathi published by Choukhamba Sanskrit bhavan Varanasi.
14. Shalakya - Vidnyan Edited by Dr.Ravindrachandra Choudhuri 2006 published by Choukhamba Oriental Varanasi.
15. Lalchandra vaidya Ashtang hrudyam of vagbhata with sarvangsundara commentary of ArunduttaVaranasi choukambha orientalia, 1977; 663.

Modern Texts

1. Principles and Practice of Ophthalmology Edited by Albert & Jakobiec. azar Gragoudas. Volume 1-2
2. Clinical Ophthalmology Jack J. Kanski 4th Edition, 2000 Butterworth - Heinmann publishers,New Dehli.
3. Parson‟s disease of Eye: Ranjitsilhota and Radhika Tondon 21th Edition, 2011, Elsevier Publication.
4. Comprehensive ophthalmology: A. K. Khurana, 6th, Jaypee Brothers Medical Publishers, New Delhi.
5. Atlas of Ocular anatomy edited by h Wakeel Ansari, Ahmed Nadeem.
6. Methods of Biostatistics: B. K. Mahajan, 6th Edition, Jaypee Brothers Medical Publishers Pvt. Ltd., Daryaganj, New Delhi.
7. Essential of ophthalmology Sumar k. Basak
8. http://www.ncbi.nlm.nih.gov/pmc/articles/pmc2720680
9. www.willseye.org/video/dry-eye-intr