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A CLINICAL STUDY ON THE EFFECT OF SAPTAMRUTA LAUHA IN THE MANAGEMENT OF TIMIRA, WITH SPECIAL REFERENCE TO SIMPLE DEVELOPMENTAL MYOPIA

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ABSTRACT

The privilence of Blindness due to Timira (Myopia) is slightly higher in rural as compare to urban area, it constitutes 2% of total population. Considering our effort to ameliorate blindness by 2020 A.D. we should also foucs our attention towards prevention and cure of blindness due to Timira. Total 100 patients of simple developmental myopia were selected and registered according to the plan of study and divided into two groups. 50 patients of trial group Saptamrita loha 500 mg BD was given orally with Grita and Madhu daily, while in placebo group Arraroot powder was given for 3 months. Statistical analysis shows that the trial drug (Saptamrita loha) is significantly effective to reduce the headache, eye strain and visual acuity with p value (<0.001) but clinically we have observed that out of 50 patients, 15 patients has been cured, 09 patients have moderate improvement and mild improvement seen in 15 patients after treatment of 90 days. Where as placebo drug was not able to reduce the sign and symptoms of simple developmental myopia.

KEYWORDS: Timira, Myopia, Saptamrita Loha, Haritaki, Vibhitaki, Amaliki.

INTRODUCTION

The diseases of eye have got almost equal importance, as compared to other bodily diseases. The most disastrous termination of ocular diseases is blindness. Myopia is the commonest cause of gradual blindness in the younger age groups. Refractive errors including myopia account for more than 7 % of the total causes of blindness in India. The condition usually begins to be noticed during the school years and the percentage rises steadily with increasing age group. The majority of cases merely result as variants in the axial length and curvature, the former being most

important although curvature myopia occurs commonly as a factor in astigmatism. Such cases of simple myopia are in no sense pathological; there will not be any degenerative changes in the fundus. Although peripheral retinal degeneration often becomes evident in later life, they do not progress after adolescence when a degree of 5 or 6 dioptres is attained.

The future of each patient with myopia should be considered as threatened loss of vision, as progressive high myopia leads to rapid deterioration of vision, sharply reduces the range of professional accessibility to a person and often ends in disability. Myopia is a condition, which may last throughout one's life and is responsible for loss of talented people in a given profession. Many educational establishments and high technical institutions reject the persons with high myopia.

Myopia creates a great problem among the student community. The spectacles, which are used to correct the errors, neither cure nor prevent the progression of the pathology; instead they create a lot of everyday inconvenience. Moreover, the spectacles are serious hindrance for an individual to participate in many sports and professions.

As far as modern medical science is concerned, no satisfactory medical treatment is available till date, for myopia. Acharya Govinddas Sen in Bhaishjya Ratnavali has recommended *'Saptamrit Lauh'* for the management of Timira. Nutritive factors also have a vital role in the management of Timira. In Ayurveda, the *Chakshushya* properties of certain drugs like *Triphala, Yasthimadhu, Luah Bhasma*, etc. are proven. So a combination of the above said drugs, in the form of oral supplement, will play a definite role in the management of refractive errors.

Promotion of visual acuity is considered as one of the priorities in Shalakya Tantra. The classics of ancient Indian wisdom have invented and practiced many drugs, procedures, diet and regimen for the benefit of weak eyes. Sufficient works have already been done on *Timira* and its management with *Chakshushya* drugs, whereas very little work has been carried out on the role of *Saptamrit Lauh* in *Timira* with special reference to simple developmental myopia and this necessitated toundertake the study in detail.

LITERARY REVIEW

Simple developmental myopia usually begins between the ages of 7 to 10 years and may increase during the years of growth until stabilizing around 25 years. Usually it is seen in school going children and college students at about –5 D or less and never exceeds – 8 D. Its prevalence have been noted in the thesis from theoretical, practical and clinical point of view in a systematic way with both ancient and modern light along with conceptual analysis and due references.

DRUG REVIEW

The drug reference is taken from Bhaishjya Ratnavali, netra rogadhikar written by Govind Das Sen. त्रिफलारज आयसं च चूर्णं सह यष्ठीमधुकं समांशयुक्तं मधुना हविषा सदा दिनान्ते पुरषो निष्यरिधरमाददीत। तिमिरक्षतरक्तराजिकण्डूक्षणदान्ध्यार्बुद.,बैण्64ध्232.236द्धण

The drug Saptamrita loha contains Haritaki, Vibhitaki, Amaliki, Yashtimadhu, Loha Bhasma and its Anupan is Grita and Madhu in improper proportion.

1. Haritaki (Terminalia chebula)

अक्षिरोगे अभया शस्ता.....(भा.प्र.1/1/12)

चक्षुष्या लघुरायुष्या.....(भा.प्र.1/1/20)

The dry nut's peel is used to cure cold-related nagging coughs. The bark/peel of the nut is placed in the cheek. Although the material does not dissolve, the resulting saliva, bitter in taste, is believed to have medicinal qualities to cure cold related coughs. Its fruit has digestive, anti-inflammatory, anthelmintic, cardiotonic, aphrodisiac and restorative properties and is additionally beneficial in flatulence, constipation, piles, cough and colds. It contains terflavin B, a type of tannin while chebulinic acid is found in the fruits.

Constituents:- Researchers have isolated a number of glycosides from Haritaki, including the triterpenes arjunglucoside I, arjungenin, and the chebulosides I and II. Other constituents include a coumarin conjugated with gallic acids called chebulin, as well as other phenolic compounds including ellagic acid, 2,4-chebulyl-β-D-glucopyranose, chebulinic acid, gallic acid, ethyl gallate, punicalagin, terflavin A, terchebin, luteolin, and tannic acid Chebulic acid is a phenolic acid compound isolated from the ripe fruits. Luteic acid can be isolated from the bark.

2. Vibhitki: (Terminalia belerica)

रुक्षं नेत्रहितं केश्यं.....(भा.प्र.1/1/37)

The pulp of the fruit (Beleric myrobalan) is considered by Hindu physicians to be astringent and laxative, and is prescribed with salt and long pepper in affections of the throat and chest. As a constituent of the triphala (three fruits), i.e., emblic, beleric and chebulic myrobalans, it is employed in a great number of diseases, and the kernel is sometimes used as an external application to inflamed parts. On account of its medicinal properties the tree bears the Sanskrit synonym of Anila-ghnaka, or "wind-killing." According to the Nighantas the kernels are narcotic.

Constituents:- Saponins, Tannin- gallic acid, ellagic acid, Cardiac glycosides- bellericanin.

3. Amaliki (Phyllanthus emblica)

हरीतकीसमं धात्रीफलं.....(भा.प्र.1/1/39)

Constituents:- Although these fruits are reputed to contain high amounts of ascorbic acid (vitamin C), 445 mg/100g, the specific contents are disputed, and the overall antioxidant strength of amla may derive instead from its high density of ellagitannins such as emblicanin A (37%), emblicanin B (33%), punigluconin (12%) and pedunculagin (14%). It also contains punicafolin and phyllanemblinin A, B, C, D, E and F. The fruit also contains other polyphenols: flavonoids, kaempferol, ellagic acid and gallic acid.

4. Yashtimadhu (Glycyrrhiza glabra)

यष्टी हिमा गुरुः स्वाद्वी चक्षुष्या बलवर्णकृत्। (भा.प्र.1/1/146)

Constituents:- The compounded carbenoxolone is derived from liquorice. Some studies indicate that it inhibits 11β-Hydroxysteroid dehydrogenase type 1, an enzyme that is highly expressed in liver and fat tissues, where it plays a role in metabolism, and in the brain, where the same enzyme is involved in stress response that has been associated with age-related mental decline.

5. Loha Bhasma- Iron is a chemical element with the symbol of Fe (Latin:ferrum) and atomic number 26. Iron is a group 8 and period 4 elements. Iron is a lustrous, silvery soft metal. It is one of the few ferromagnatic elements. Iron and nickel are notable for being the final elements produced by stellar nucleosynthesis, and are therefore the heaviest elements which do not require a red giant or supernova for formation. Iron and nickel are therefore the most abundant metals in metallic meteorites and in the dense-metal cores of planets such as Earth. Iron and Iron alloys are also the most common source of ferromagnetic materials in everyday use.

6. Ghrita

Hindi – Ghee

English – Clarified butter

Synonyms – *Aajya, Havis, Sarpis*.

Properties

Rasa – Madhura

Guna – Guru, Snigdha, Mridu

Veerya – Sheeta

Vipaka – Madhura

Dosha karma – Vata-Pitta shamana

Action and Uses- *Medhya, Rasayana, Vrshya, Swarya, Chakshushya,Balya.*

7. Madhu

English name - Honey

Sanskrit name – Madhu, Makshika

Properties

Rasa – Madhura, Kashaya

Guna – Guru, Ruksha, Sheeta

Veerya – Ushna

Vipaka – Katu

Dosha karma –Pitta-kapha shamana

Action and Uses- Chakshushya, lekhaniya, Balya

CLINICAL STUDY

There is no satisfactory medical treatment for the management of Timira (simple developmental myopia) as far as the modern medical science is concerned and the treatment is mainly directed to spectacle correction, contact lenses or surgery. Ayurveda has mentioned some effective remedies for the management of *Timira*. The response of the medications can be easily assessed with the help of modern science. Because of these reasons, the disease *Timira* with special reference to simple developmental myopia is selected for present study.

AIM AND OBJECTIVES

A clinical trial was carried out with the following aims and objectives:

a) To study the aetio-pathogenesis of *Timira* in accordance with modern descriptions and to establish a correlation between *Timira* and simple developmental myopia.

b) To explore the efficacy of *Saptamrita Loha* in the management of simple developmental myopia and to understand their indications and contraindications from clinical point of view.

c) To find out the efficacy of *Saptamrita Loha* as an oral supplement in the promotion of visual acuity.

MATERIALS AND METHODS

It is a randomized clinical study, The study is strictly confined to Simple developmental Myopia and their clinical management. The conceptual study, ancient description and life-long survey identifying simple developmental Myopia as the material of study.

A. Selection of sample:- In this clinical study the patient will be selected from outdoor and indoor patient department of Shalakya tantra, Government Ayurveda college and hospital, Rewa and from camps organized by the college.

B. Sample size:- 100 patients were selected for the purpose of study. All the patients are divided in two groups. Each group has 50 patients.

Group A)- 50 patients in this trial group were treated with Saptamrita lauha.

Group B)- 50 patients in this placebo group were treated with Arraroot powder.

C. Study design:- 100 cases were selected for the study and divided into two groups, one is placebo and another is trail group. The clinical features before treatment were compared with clinical feature after treatment, to know the effectiveness of the drug.

D. Parameters of observation:- With the help of Snenel's chart, change of visual acuty will be measured.

E. Inclusion criteria-

a) Age- between 12 years to 25 years.

b) Sex- either sex

c) Patient with simple developmental myopia within the range -0.25D to 6 D of one eyed or homogeneously effected eyes.

F. Exclusion criteria

a) Patient associated with local eye disorders.

b) Patients associated with systemic diseases.

c) Patient who are less than 12 years and more than 25 years.

G. Withdrawal criteria- During the course of the treatment, if any serious conditions or any adverse effect occurs or if patient himself/herself want to withdraw from study. Such patient may be withdrawn from the study.

H. Drugs:- Saptamrutalauha is used for the proposed clinical study in trial group and Arraroot powder is used for the placebo group.

Drug doses and Route of administration:- Saptamrita lauha is given orally in doses 500 mg twice daily to the patients of trail group and Arraroot powder is given to the placebo group patient orally of 500 mg twice daily.

Duration of treatment:- The duration of treatment is for 3 months.

I. **Method:-** 100 cases were selected for the study and divided into two groups -Trial group and Placebo group, in each group 50 cases are taken. In trial group, the treatment one -T_1 , the sign and symptoms before treatment were compared with the sign and symptoms of after treatment to know the effectiveness of trail drug.

Similarly in placebo group the treatment two -T_2, the sign and symptoms before treatment were compared with the sign and symptoms of after treatment to know the effectiveness of placebo drug.

T_1 (B.T.) –Vs- T_1 (A.T.)

To know the effectiveness of treatment-I (Trail group)

T_2 (B.T.) – Vs- T_2 (A.T.)

To know the effectiveness of treatment-II (Placebo group)

B.T. = Before treatment

A.T. = After treatment

The method of research work is divided into 3 phases:

1- Diagnosis Phase:- The diagnosis of myopia has been done on the basis of various clinical investigations, the findings of which were recorded in a special research proforma, prepared as per Ayurvedic and modern parameters. A thorough external examination of the eye has been done to rule out any abnormalities in conjunctiva, sclera, cornea, lacrimal apparatus, iris, lens and pupil. The conjugate ocular movements were tested in six cardinal positions.

The visual acuity was tested by means of Snenell's test types, kept 6 meters away from the patient with good illumination. The improvement in visual acuity after holding pinhole disc was recorded. Objective assessment of refraction was done by retinoscopy after full mydriasis. Computerised Autorefractometer is used to verify the findings of retinoscopy. Fundoscopy was done with direct ophthalmoscope after full mydriasis.

Routine blood, urine and stool investigations were carried out to rule out any systemic pathology.

2-Interventional Phase:- The study was intervened by the treatment with *Saptamrit Loha* to 50 patients of age group of 12-25 years 1 g. per day in two divided doses for the trial group and 50 patients by Arraroot powder for placebo group 1g/day in two divided doses. The treatment was continued continuously for 03 months.

The patients were also advised to take cold water for head bath. It was advised to rub the dorsal aspect of the foot (*Padatala*) with oil. Intake of green gram was suggested along with their routine food items. Too much of salty, sour, bitter, hot and pungent items, oily food preparations etc. were restricted.

Follow up study: Follow up study was undertaken for every 01 month.

3 - Assessment Phase:- The effect of treatment was assessed by clinical observations as well as on the basis of investigation reports.

Criteria for assessment

Objective: Clinical refraction by means of:

- Retinoscopy
- Autorefractometer.

Subjective

- Snellen's Chart Reading
- Improvement in signs and symptoms.

The results were assessed as follows- Gradation scale of sign & symptoms for the assessment of simple developmental myopia.

(a) Visual Acuity and gradation:- Visual acuity was recorded as numerical values and later converted into percentage as per the methods of Kaith Lyle et al. 1985.

Snellen's Chart reading	Percentage	Grade
6/6	100	0
6/9	90	1
6/12	80	1
6/18	60	2
6/24	50	2
6/36	40	3
6/60	20	3

(b) Subjective symptoms:- Subjective symptoms were assessed with the help of following scoring techniques:

S. N.	Symptoms	G0	G1	G2	G3
1.	Headache	No headache	Very occasional headache	Irregular attacks of frequent	headache Regular headache
2.	Eyestrain	After more than 6 hours of near work	After 4 – 6 hours of near work	After 2 – 4 hours of near work	Before 2 hours of near work
3.	Diplopia	No diplopia	Occasional diplopia	Regular diplopia without disturbing routine work	Regular diplopia disturbing day-to-day work

Gradation for assessment of Subjective parameters:- For the assessment of result we have used some grade points considering the severity of different signs and symptoms as follows

Nature of Severity	Grade	Grade points
Severe	G 3	3
Moderate	G 2	2
Mild	G 1	1
Normal	G 0	0

CLINICAL ASSESSMENT OF RESULT

a) Complete Cure:- Total disappearance of myopia, means he/she is able to read the snenel's chart in the naked Eye from top to bottom.

b) Maximun improvement:- Three or more than three lines improvement of reading in the snenel's chart with reduction of other sign and symptoms.

c) Moderate improvement:- Two or less than three lines improvement of reading in snenal's chart with reduction of other sign and symptoms.

d) Mild improvement:- One or less than two lines improvement of reading in the snenal's chart with reduction of other sign and symptoms.

e) Statistical assessment of result:- Mean ± S.D. of sign and symptoms of trial and placebo group have been compared with before and after treatment. The paired t-test used for the purpose of the significance and the effectiveness of trial and placebo group is assessed through P value.

OBSERVATION AND RESULT

Clinical aspects approaching for the treatment among all the patients are respected showing the incidence of statistical analysis and effectiveness of trial drug along the clinical result etc. Data of each item as explained are presented in the tabular and graphic form with footnotes.

Table 1: Completion wise distribution of 100 patients of Simple Myopia.

Completion wise	No. of patients		Total	Percentage
	Group I	Group II		
Completed	50	45	95	95
LAMA	00	05	05	05

In this clinical study on Simple Myopia, a total number of 100 patients were registered and were categorized into two groups, comprising of 50 patients in trial group and 50 patients in placebo group. Out of these, 95 patients were completed the whole treatment and 5 patients in placebo group were discontinued the treatment against medical advice.

So the observations quoted from here onwards include the data of 95 patients only, who had completed the whole treatment and follow up period.

Table 2: Age wise distribution of 95 patients of Myopia.

Age in years	No. of patients		Total	Percentage
	Group I	Group II		
12-15	08	10	18	18.94
15 – 18	14	12	26	26.36
18 – 21	16	11	27	28.42
21 – 25	12	12	24	25.26

Patients between the age group of 12 – 25 years were selected for the clinical study. The above table reveals that majority of the patients (28.42%) were reported in the age group of 18 – 21 years followed by 26.36% in the age group of 15 – 18 years, 25.26% in the age group of 21-25 years, 18.94% in 12-15 years age group.

Table 3: Sex wise distribution of 95 patients of Myopia.

Sex	No. of patients		Total	Percentage
	Group I	Group II		
Male	21	14	35	36.84
Female	29	31	60	63.16

It is observed from the above table that there was a female sex group predominance (63.16%) followed by 36.84% male sex group.

Table 4: Religion wise distribution of 95 patients of Myopia.

Religion	No. of patients		Total	Percentage
	Group I	Group II		
Hindu	32	30	62	31.57
Muslim	12	09	21	22.10
Christian	02	01	03	03.15
Others	04	05	09	9.47

The above table reveals that a maximum 31.57% of the patients were Hindus, followed by 22.10% of Muslims, 03.15 % of Christians and 9.47% of other religions.

Table 5: Occupation wise distribution of 95 patients of Myopia.

Occupation	No. of patients		Total	Percentage
	Group I	Group II		
Student	35	33	69	72.63
Service	03	01	04	04.21
House wife	06	05	11	11.57
Others	06	06	12	12.63

The above table illustrates that a maximum 72.63% of the patients were students followed by 12.57% of others, 11.57% of housewives and 04.21% of service persons.

Table 6: Education wise distribution of 95 patients of Myopia.

Education	No. of patients		Total	Percentage
	Group I	Group II		
Primary	08	00	08	08.42
Matriculation	12	15	27	28.42
Higher secondary	14	26	40	42.10
Graduate	11	04	15	15.78
Post graduate	05	00	05	5.26

From the above table, it is revealed that maximum 42.10% of the patients were having higher secondary education, followed by 28.42% having matriculation, 15.78% having graduation, 08.42% having primary education and 05.26% having post graduation.

Table 7: Marital status wise distribution of 95 patients of Myopia.

Marital status	No. of patients		Total	Percentage
	Group I	Group II		
Married	09	12	21	22.22
Unmarried	41	33	74	77.78

Out of the 95 patients registered for the present clinical study, 22.22% of the patients were unmarried and 77.78% of the patients were married.

Table 8: Socio-economic status wise distribution of 95 patients of Myopia.

Socio-economic status	No. of patients		Total	Percentage
	Group I	Group II		
Poor	15	10	25	26.31
Lower middle	18	20	38	40
Middle	10	09	19	20
Upper middle	05	05	10	10.52
Rich	02	01	03	03.15

The above table illustrates that maximum number of patients i.e. 40% were belonging to lower middle class followed by 26.31% in poor class, 20% in middle class, 10.52% in upper class and 03.15% of the patients in rich socio-economic class.

Table 09: Diet wise distribution of 95 patients of Myopia.

Diet	No. of patients		Total	Percentage
	Group I	Group II		
Vegetarian	37	34	71	74.73
Mixed	13	11	24	25.26

The above table shows that maximum number of patients i.e. 74.73% were vegetarians followed by 25.26% of the patients taking mixed diet.

Table 10: Addiction wise distribution of 95 patients of Myopia.

Addiction	No. of patients		Total	Percentage
	Group I	Group II		
Tea/Coffee	31	25	56	58.94
Smoking	07	09	16	16.84
Tobacco	02	03	05	05.26
Alcohol	01	00	01	01.05
No addiction	09	08	17	17.89

The above table shows that, maximum number of the patients, i.e. 58.94 % were addicted to tea or coffee, followed by 17.89% patients having no addiction, 16.84% addicted to smoking, 05.26 % addicted to tobacco chewing and 01.05% addicted to alcohol.

Table 11: Reading hours per day wise distribution of 95 patients of Myopia.

Reading hours / day	No. of patients		Total	Percentage
	Group I	Group II		
1 –<4 hours	34	35	65	68.42
4 –<6 hours	11	07	23	24.21
6 – <9 hours	05	03	07	07.36
9 -10 hours and above	00	00	00	00

It is observed that maximum number of patients i.e. 68.42% were having 1 – <4 hours of reading per day followed by 24.21% having 4 – <6 hours reading and 7.36 % having 7 – <9 hours of reading per day.

Table 12: Sleep wise distribution of 95 patients of Myopia.

Sleep	No. of patients		Total	Percentage
	Group I	Group II		
Sound	32	36	68	71.57
Disturbed	18	09	27	28.42

The above table reveals that a maximum number of patients i.e. 71.57% were having sound sleep followed by 28.42% of the patients having disturbed sleep.

Table 13: Habitat wise distribution of 95 patients of Myopia.

Habitat	No. of patients		Total	Percentage
	Group I	Group II		
Urban	09	07	16	16.48
Rural	41	38	79	83.15

The above table reveals that maximum number of patients i.e. 83.15% were reported to be of rural habitat followed by 16.48% belonging to urban area.

Table no.14a: Showing the % relief in Visual Acuity in 50 patients before and after treatment in trail group.

Grade	At the time of selection	after 30 days	After 60 days	After 90 days
	BT`	A.T.	A.T.	A.T.
G 0	00	00	00	05
G 1	29	29	29	30
G 2	17	17	17	11
G 3	04	04	04	04

Out of 50 patients with symptom of visual acuity, there was 5 patients got relief from grade 1 to grade 0 after treatment of 90 days while 6 patients have got relief from grade 2 to grade 1 and grade 3 patients have remained unchanged after 90 days of treatment.

Table no.14b: Showing the % relief in Visual Acuity in 45 patients before and after treatment in placebo group.

Grade	At the time of selection	After 30 days	After 60 days	After 90 days
	BT	A.T.	A.T.	A.T.
G 0	00	00	00	00
G 1	26	26	26	26
G 2	15	15	15	15
G 3	04	04	04	04

Out of 45 patients with symptom of visual acuity, there was no relief in any grade after treatment of 90 days.

Table no.15a: Showing the % relief in Headache in 50 patients before and after treatment in trial group.

Grade	At the time of selection	After 30 days	After 60 days	After 90 days
	BT	A.T.	A.T.	A.T.
G 0	30	30	30	44
G 1	20	20	20	06
G 2	00	00	00	00
G 3	00	00	00	00

Out of 50 patients with symptom of headache, there was 14 patients got relief from grade 1 to grade 0 after treatment of 90 days.

Table no.15b: Showing the % relief in Headache in 45 patients before and after treatment in placebo group.

Grade	At the time of selection	After 30 days	After 60 days	After 90 days
	BT	A.T.	A.T.	A.T.
G 0	30	30	30	32
G 1	15	15	15	13
G 2	00	00	00	00
G 3	00	00	00	00

Out of 45 patients with symptom of Headache, there were 2 patients have got relief from grade 1 to grade 0 after 90 days of treatment.

Table no. 16a: Showing the % relief in Eye strain in 50 patients before and after treatment in trial group.

Grade	At the time of selection	after 30 days	after 60 days	After 90 days
	B.T.	A.T.	A.T.	A.T.
G 0	15	15	15	19
G 1	08	08	08	09
G 2	10	10	10	14
G 3	17	17	17	08

Out of 50 patients with symptom of eye strain there was 4 patients have got relief from grade 1 to grade 0 while 5 patients have got relief from grade 2 to grade 1 and 9 patients have got grade 3 to grade 2 after 90 days of treatment.

Table no. 16b: Showing the % relief in Eye strain in 45 patients before and after treatment in placebo group.

Grade	At the time of selection	After 30 days	After 60 days	After 90 days
	B.T.	A.T.	A.T.	A.T.
G 0	15	15	15	18
G 1	08	08	08	05
G 2	07	07	07	07
G 3	15	15	15	15

Out of 45 patients with symptom of eye strain there was 3 patients have got relief from grade 1 to grade 0 while grade 2 and grade 3 patients have remained unchanged after 90 days of treatment.

Table 17: Statistical analysis is showing the effectiveness of trail drug to different sign and symptoms.

Symptoms	Mean score			% of Relief	S.D. (±)	S.E. (±)	't'	P
	B.T.	A.T.	BT-AT					
Visual Acuity	1.5	1.14	0.36	24	0.464	0.067	4.343	<0.001
Headache	0.4	0.12	0.28	70	0.453	0.064	4.374	<0.001
Eyestrain	1.52	1.16	0.36	24	0.484	0.068	5.294	<0.001

The initial mean score in the symptom visual acuity was recorded as 1.5 which is reduced to 1.14 after therapy. The percentage of relief was observed as 24%. The result was statistically highly significant (P <0.001). The headache was recorded as 0.4, which reduced to 0.12 after therapy. The percentage of relief was observed as 70%. The result was statistically highly significant (P<0.001). The initial mean score of the symptom eyestrain was recorded as 1.52, which reduced to 1.16 after therapy. The percentage of relief was 24% and the result was statistically highly significant (P<0.01).

Table no. 18a: Showing the % relief through clinical assessment in 50patients after treatment in trail group.

Clinical Assessment	After 30 days	After 60 days	after 90 days	%
Cured	0	0	15	30
Maximum improvement	0	0	0	0
Moderate improvement	0	0	9	18
Mild improvement	0	0	15	30
No improvement	50	50	11	22

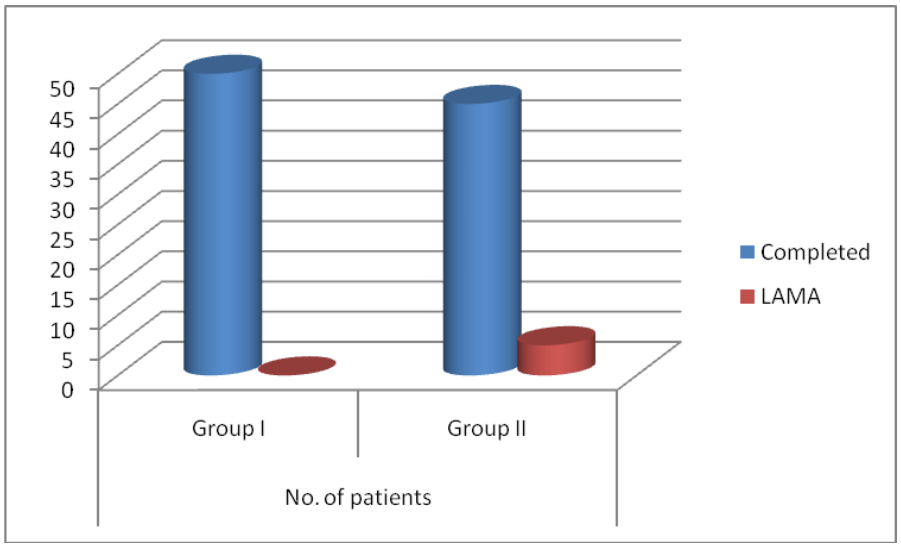
Out of 50 patients of myopia, there were 15 patients has been cured and 09 patients have been got moderate improvement after treatment of 90 days and 15 patients were got mild improvement while only 11 patients were got no improvement after 90 days of treatment.

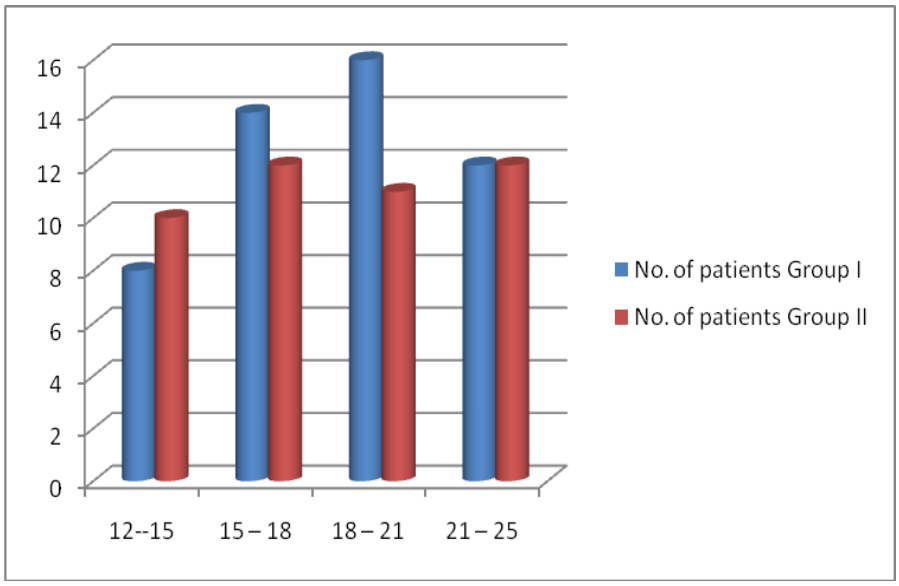
Out of 50 patients of myopia, there were 30% patients has been cured and 18% patients have been got moderate improvement after treatment of 90 days and 30% patients were got mild improvement while only 22% patients were got no improvement after 90 days of treatment.

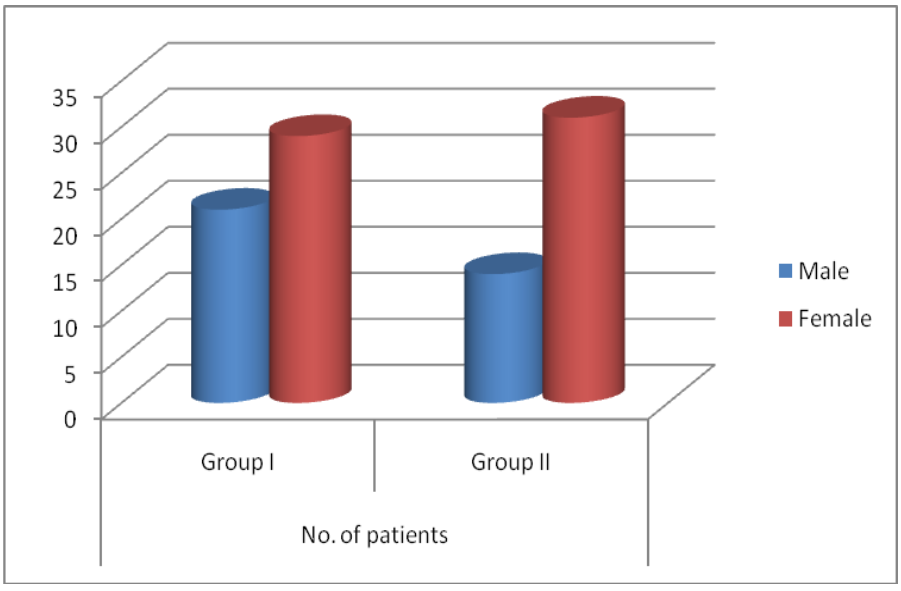
Table no. 18b: Showing the % relief through clinical assessment in 45 patients after treatment in plecebo group.

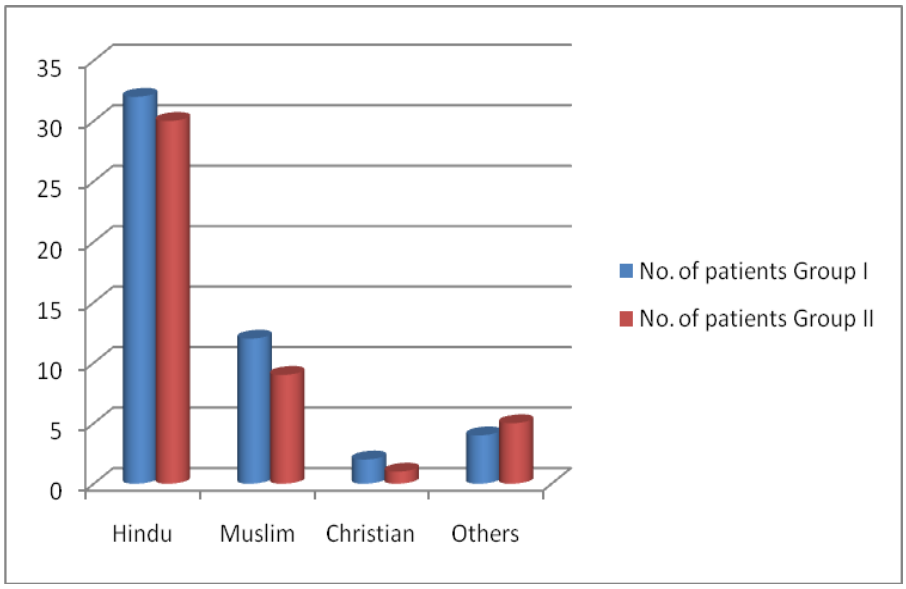
Clinical Assessment	After 30 days	After 30 days	After 90 days	%
Cured	0	0	0	0
Maximum improvement	0	0	0	0
Moderate improvement	0	0	0	0
Mild improvement	0	0	3	6.7
No improvement	45	45	42	93.3

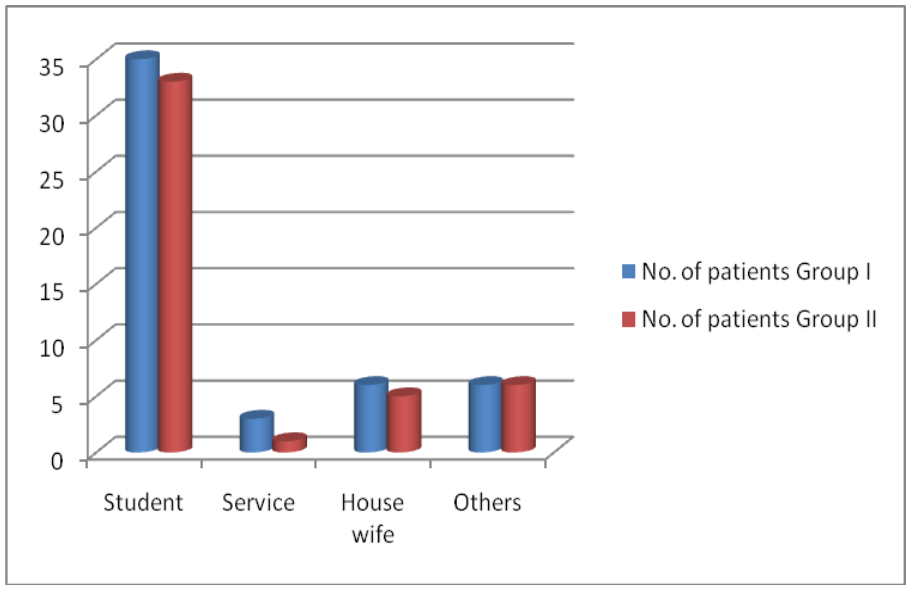
Out of 45 patients of myopia, there were only 03 patients have been got mild improvement after 90 days of treatment. Out of 45 patients of myopia, there were only 07% patients have been got mild improvement after 90 days of treatment while 93% got no improvement.

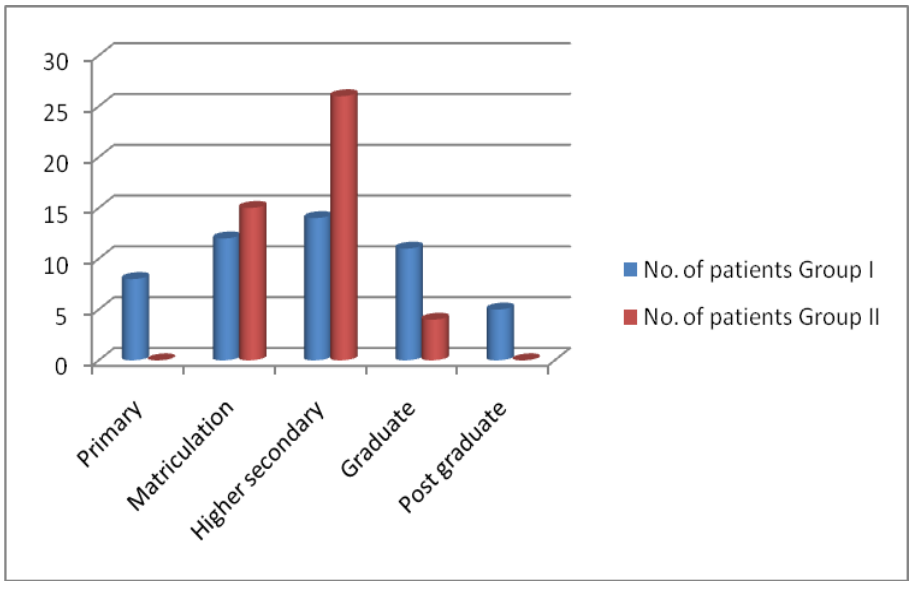

50
45
40
35
30
25
20
15
10
5
0
Group I
Group II
No. of patients
Completed
LAMA

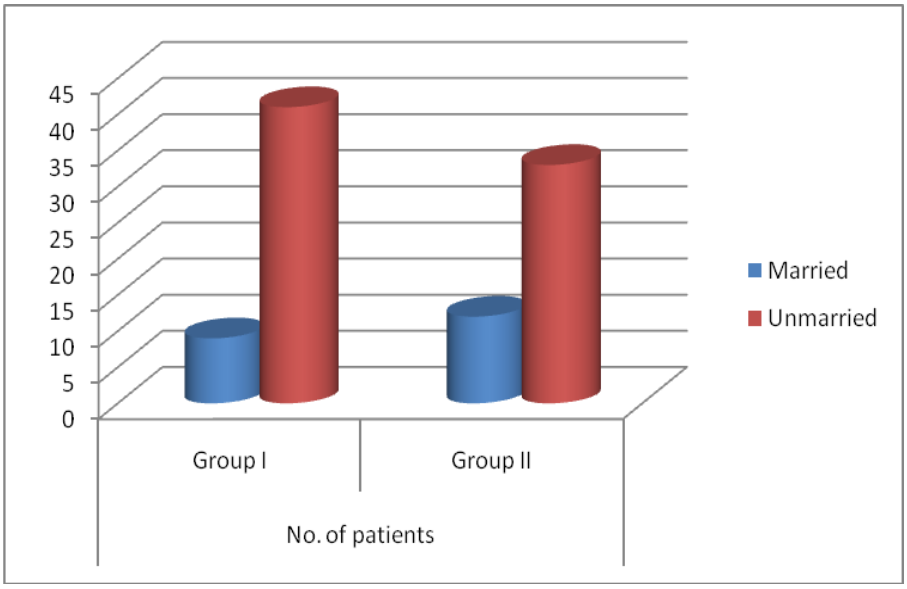

16
14
12
10
8
6
4
2
0
12--15
15 – 18
18 – 21
21 – 25
No. of patients Group I
No. of patients Group II

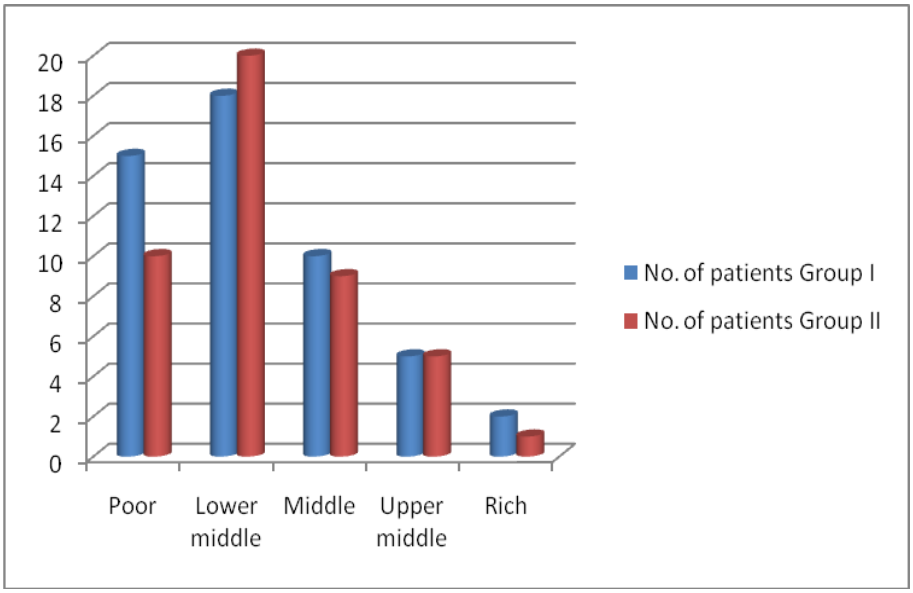

35
30
25
20
15
10
5
0
Group I
Group II
No. of patients
Male
Female

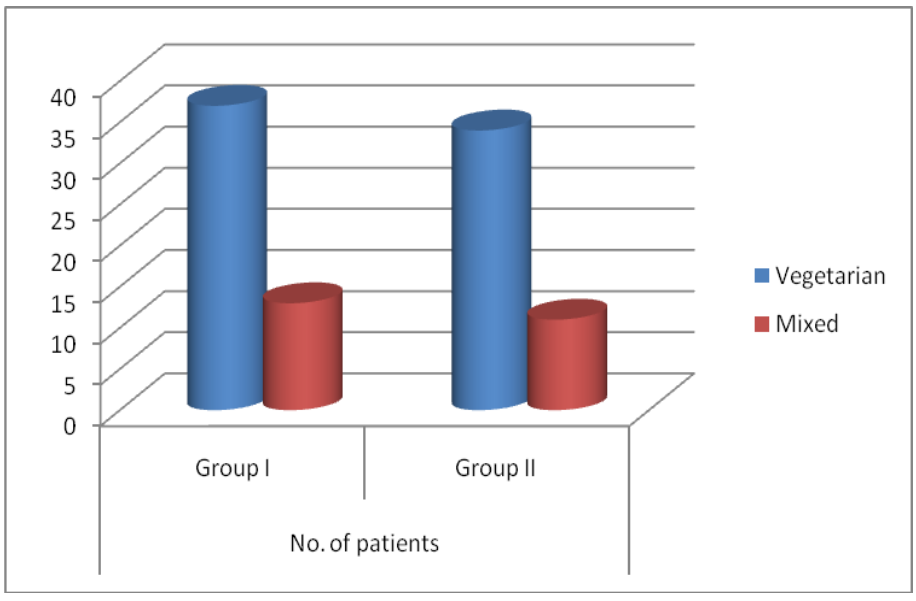

35
30
25
20
15
10
5
0
Hindu
Muslim
Christian
Others
No. of patients Group I
No. of patients Group II

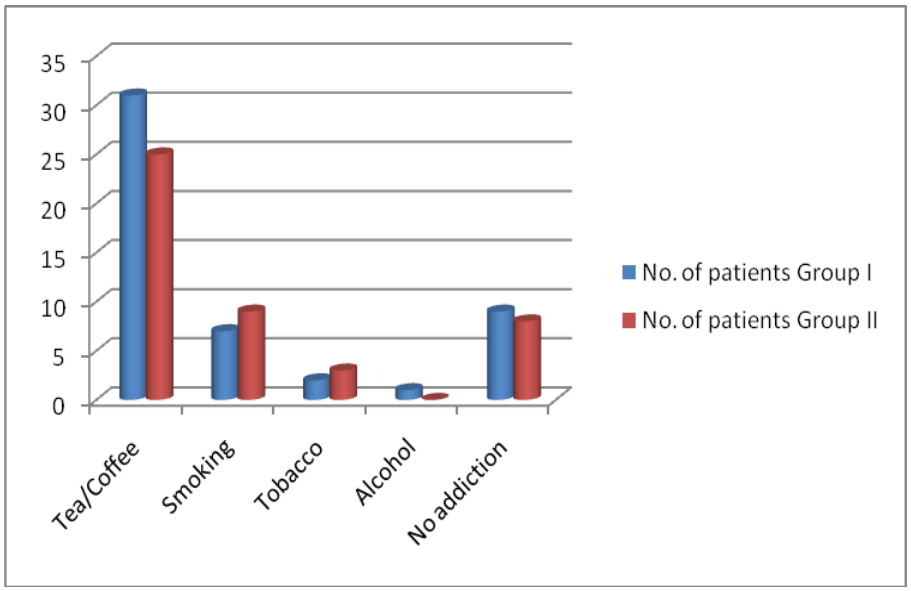

35
30
25
20
15
10
5
0
Student
Service
House wife
Others
No. of patients Group I
No. of patients Group II

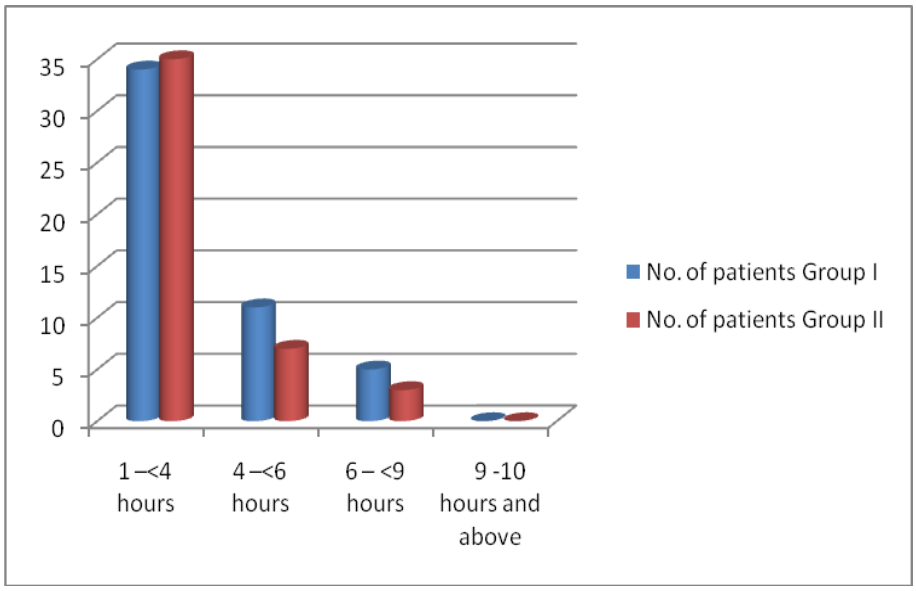

30
25
20
15
10
5
0
Primary
Matriculation
Higher secondary
Graduate
Post graduate
No. of patients Group I
No. of patients Group II

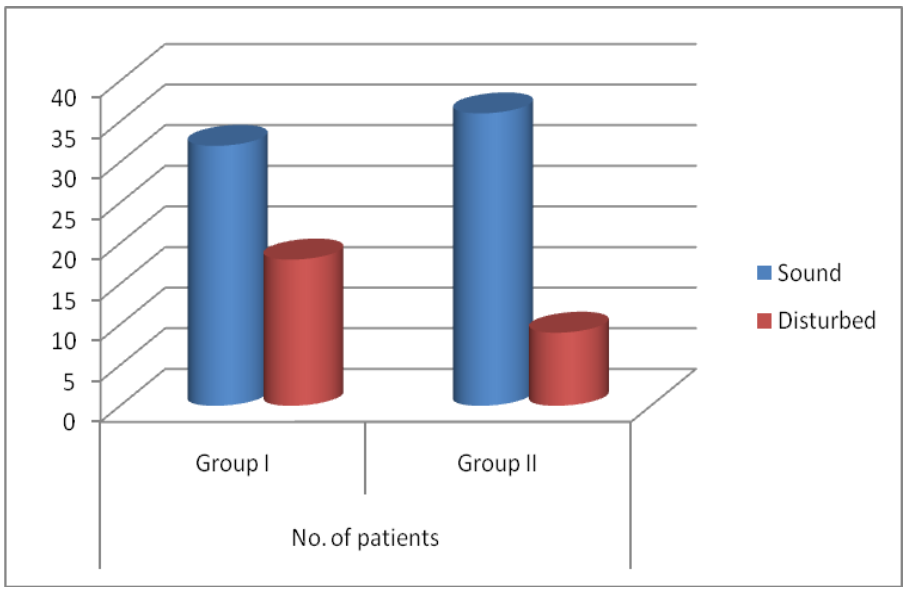

45
40
35
30
25
20
15
10
5
0
Group I
Group II
No. of patients
Married
Unmarried

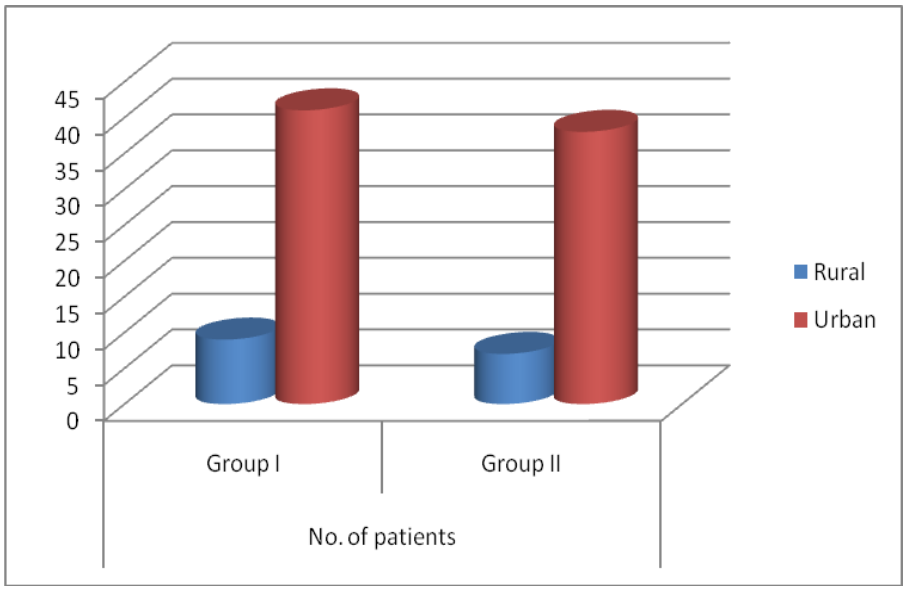

20
18
16
14
12
10
8
6
4
2
0
Poor
Lower middle
Middle
Upper middle
Rich
No. of patients Group I
No. of patients Group II

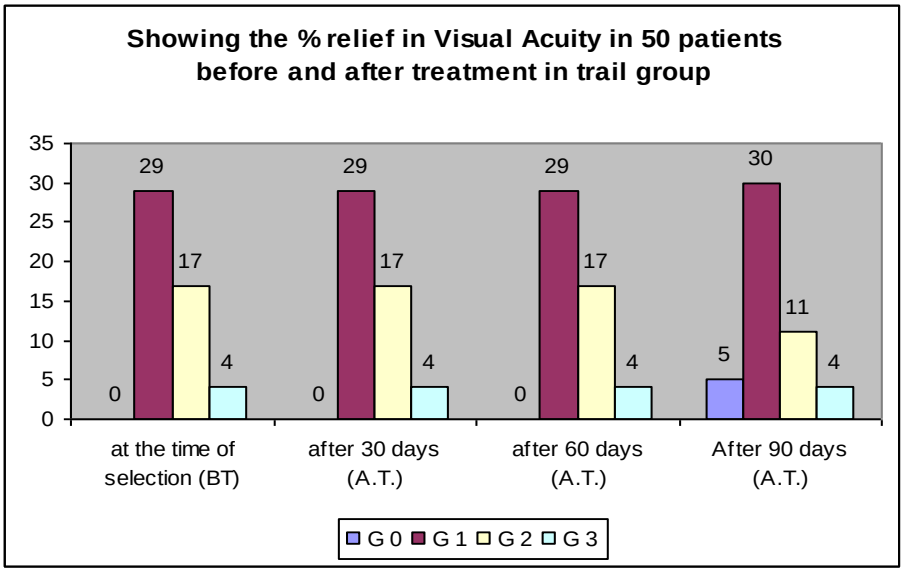

40
35
30
25
20
15
10
5
0
Group I
Group II
No. of patients
Vegetarian
Mixed

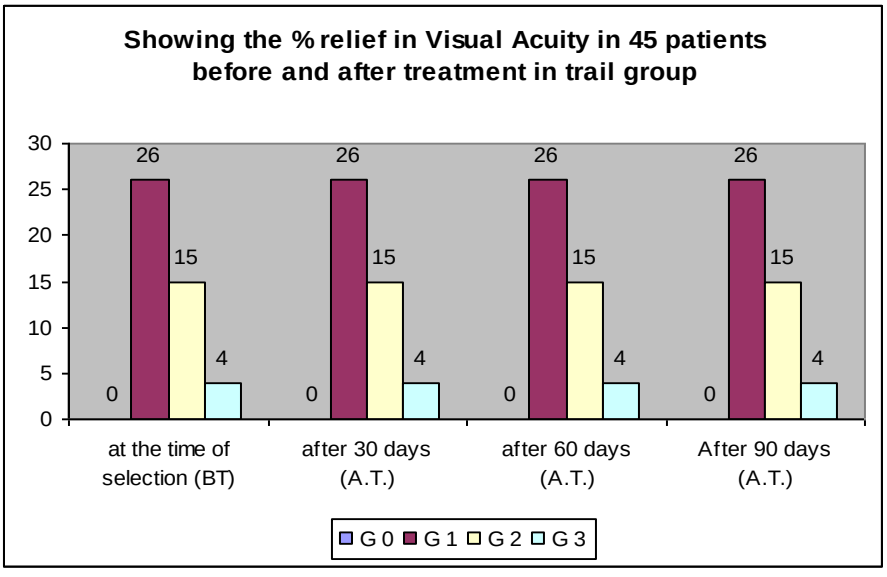

35
30
25
20
15
10
5
0
Tea/Coffee
Smoking
Tobacco
Alcohol
No addiction
No. of patients Group I
No. of patients Group II

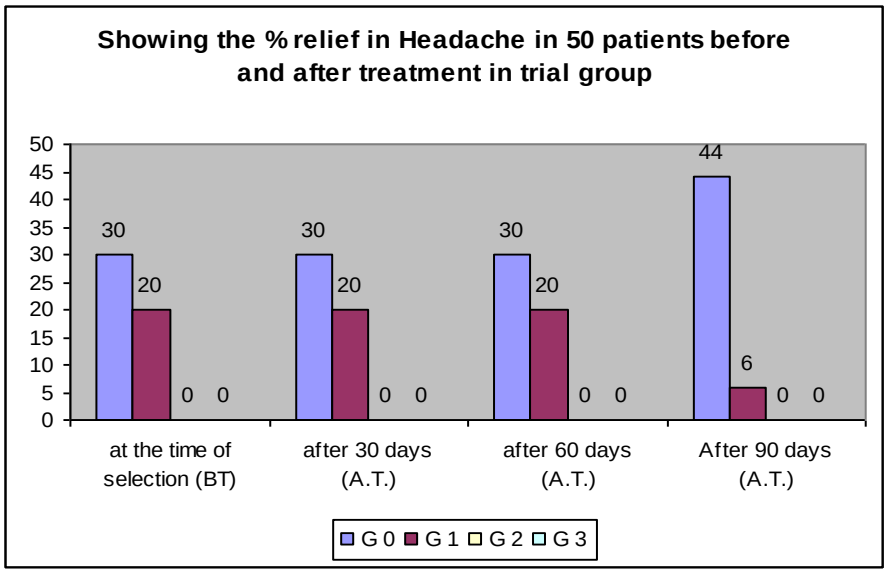

35
30
25
20
15
10
5
0
1 –<4 hours
4 –<6 hours
6 – <9 hours
9 -10 hours and above
No. of patients Group I
No. of patients Group II

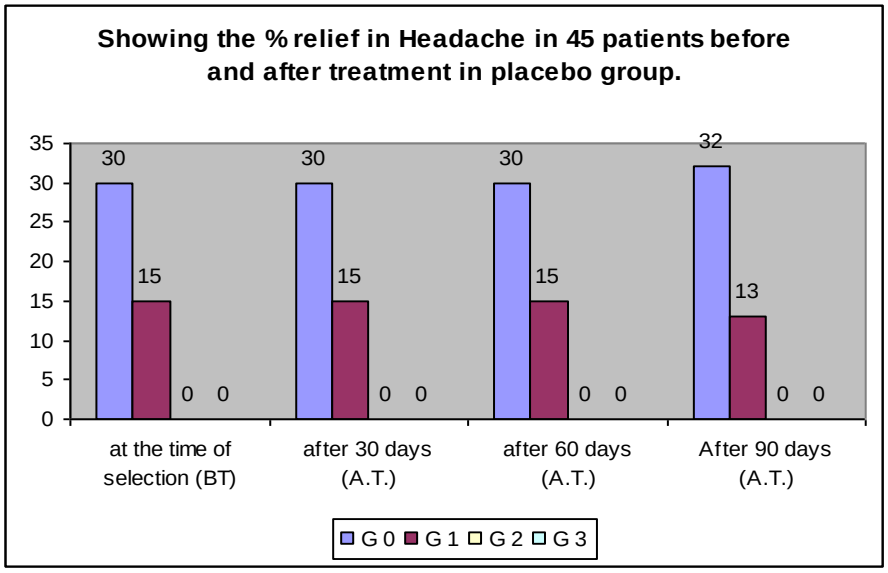

40
35
30
25
20
15
10
5
0
Group I
Group II
No. of patients
Sound
Disturbed

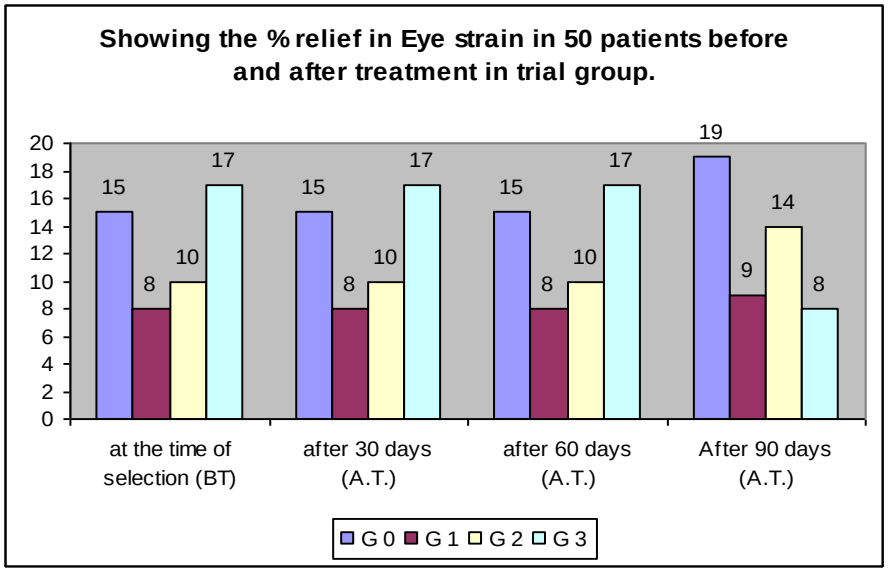

45
40
35
30
25
20
15
10
5
0
Rural
Urban
Group I
Group II
No. of patients

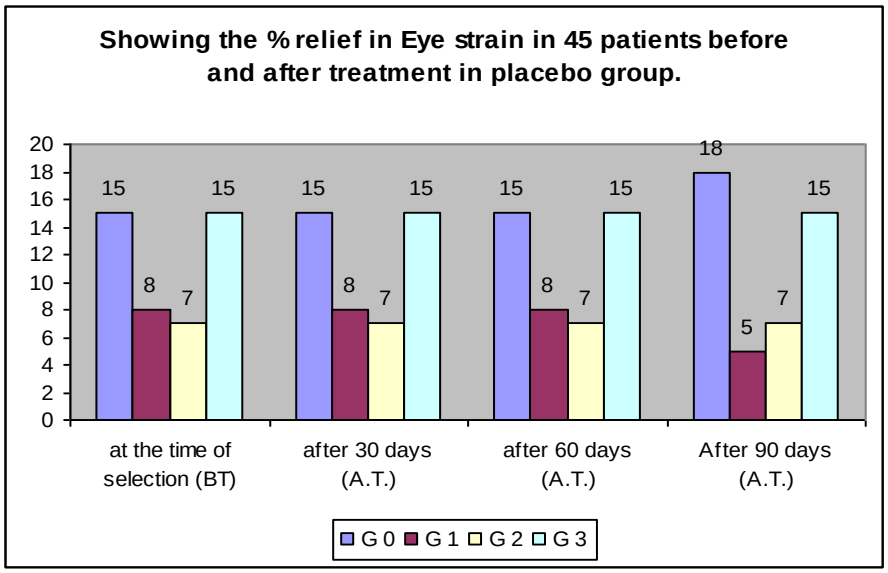

Showing the % relief in Visual Acuity in 50 patients before and after treatment in trail group
35
30
25
20
15
10
5
0
29
17
4
0
29
17
4
0
29
17
4
0
5
30
11
4
0
at the time of selection (BT)
after 30 days (A.T.)
after 60 days (A.T.)
After 90 days (A.T.)
G 0 G 1 G 2 G 3

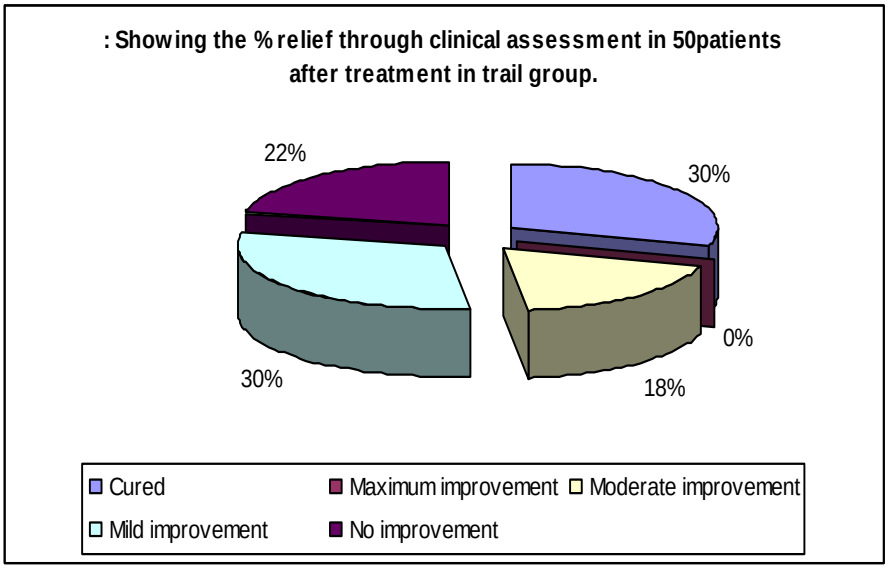

Showing the % relief in Visual Acuity in 45 patients before and after treatment in trail group
30
25
20
15
10
5
0
26
15
4
0
26
15
4
0
26
15
4
0
26
15
4
0
at the time of selection (BT)
after 30 days (A.T.)
after 60 days (A.T.)
After 90 days (A.T.)
G 0 G 1 G 2 G 3

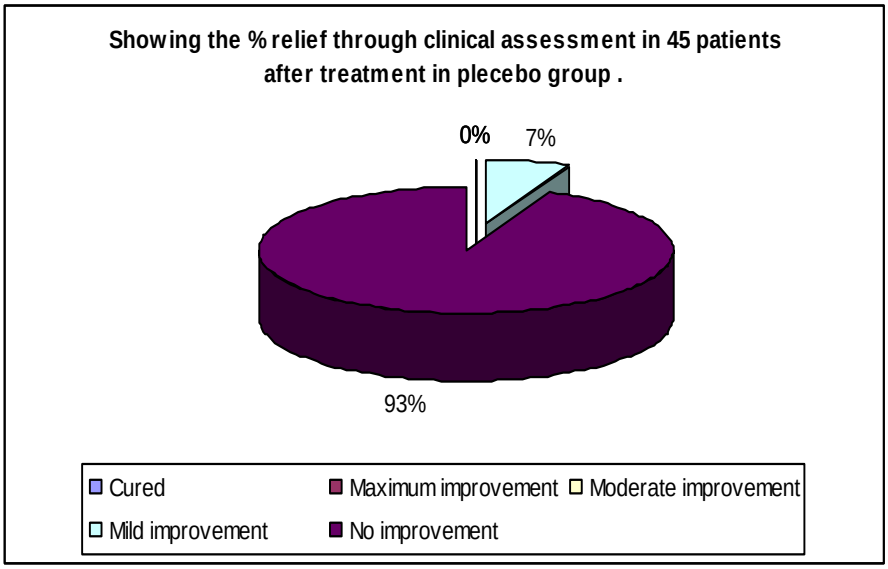

Showing the % relief in Headache in 50 patients before and after treatment in trial group
50
45
40
35
30
25
20
15
10
5
0
30
20
0
0
30
20
0
0
30
20
0
0
44
6
0
0
at the time of selection (BT)
after 30 days (A.T.)
after 60 days (A.T.)
After 90 days (A.T.)
G 0
G 1
G 2
G 3


Showing the % relief in Headache in 45 patients before and after treatment in placebo group.
35
30
25
20
15
10
5
0
30
15
0
0
30
15
0
0
30
15
0
0
32
13
0
0
at the time of selection (BT)
after 30 days (A.T.)
after 60 days (A.T.)
After 90 days (A.T.)
G 0
G 1
G 2
G 3


Showing the % relief in Eye strain in 50 patients before and after treatment in trial group.
20
18
16
14
12
10
8
6
4
2
0
15
8
10
17
15
8
10
17
15
8
10
17
19
9
14
8
at the time of selection (BT)
after 30 days (A.T.)
after 60 days (A.T.)
After 90 days (A.T.)
G 0
G 1
G 2
G 3


Showing the % relief in Eye strain in 45 patients before and after treatment in placebo group.
20
18
16
14
12
10
8
6
4
2
0
15
8
7
15
15
8
7
15
15
8
7
15
18
5
7
15
at the time of selection (BT)
after 30 days (A.T.)
after 60 days (A.T.)
After 90 days (A.T.)
G 0
G 1
G 2
G 3


: Showing the % relief through clinical assessment in 50patients after treatment in trail group.
22%
30%
0%
30%
18%
Cured
Maximum improvement
Moderate improvement
Mild improvement
No improvement


Showing the % relief through clinical assessment in 45 patients after treatment in plecebo group .
0%
7%
93%
Cured
Maximum improvement
Moderate improvement
Mild improvement
No improvement

DISCUSSION

The present study is an advance work on ophthalmology. This work deals with a vital eye disease "TIMIRA (Simple developmental myopia)". The process of detection of disease was based upon the clinical characters both from Ayurved and modern aspects.

Myopia affects an uncountable large section of the population and involves very young eyes leading to the degenerative changes terminating in blindness. No remedial measures for the prevention and care of this pathology prevails in the modern ophthalmology; opening the door to the other systems of medicine to suggest, experiment and contribute the drugs to alleviate or to check the deterioration. This challenge of the time was accepted by the *Ayurved*ic scholars, as they believed that nature provides both diseases and drug together and gave a concept of *chakshushya* for the protection, restoration and regeneration of the eyesight. It is astonishing to note that before the centuries, Kepler's description of refractive errors, *Acharya Sushruta* has quoted a similar clinical picture under the broad caption of *Timira*, a small fraction of which can be safely compared, to Myopia on the basis of following facts-

1. *Avyakta Darshana* or blurring of vision for distance and near occurs in high myopia.
2. Cardinal symptom of myopia i.e. difficulty in distant vision is there in *Timira* when the vitiated humors are lodged in the upper part of the *drishti.*
3. *Vihavala darshana* symptom occurs due to progressive myopia, which results into vitreous degeneration and ultimately retinal degeneration and detachment in advanced stage.
4. *Gochara vibhrama* or partial loss of vision is also due to vitreous liquefaction and retinal degeneration.
5. Incidence of blindness and cataract are more in myopia; *timira* also leads to *linganasha* i.e. loss of vision ultimately in which *kaphaja linganasha* has identical description to that of mature cataract.
6. *Timira* can be sequel and has not got any ocular and systemic problem except visual disturbances; myopia as such also doesn't produce any systemic effect.
7. *Timira* in which, *patala* or fine membranes, nourished by *tejojala, mamsa*, *medo*, and *asthi* are held responsible which probably related to various intraocular structures participating in accommodation and convergence. As also the myopia involves the change in the refractive indices as well as changed normal dimension of outer layer of the eye (sclera and cornea) with degenerative changes in choroid in high myopia.

The present study has involved 100 patients of myopia. The diagnosis was made on the basis of signs and symptoms described in *Ayurvedi*c and modern texts. Modern parameters were used to confirm the diagnosis. Routine haematological, stool & urine examinations were done to rule out the diabetes, worm infestation etc. in all the patients. In this clinical study the patient will be selected from outdoor and indoor patient department of shalakya tantra, Government Ayurveda College and hospital, Rewa and from camps organized by the college. There were total 100 patients had been selected for the purpose of study. All the patients were divided in two groups of 50 patients each. Trial group were treated with saptamrita loha while placebo group were treated with Arraroot powder in capsule form. The change of visual acuity was observed during regular interval of 30 days. Saptamrita loha was taken orally and given in doses 500 mg twice with Ghee, Madhu and Dugdha daily to the patients of trail group and Arraroot powder was given to the placebo group patient orally of 3 gm twice daily.The duration of treatment was for 3 months. In trial group patients were administered '*Saptamrita loha*' as orally in the dose of 500 mg twice in a day for 90 days continuously while in placebo group patients were administered Arraroot powder orally in capsule of 500mg twice in a day for 90 days continuously.

For the assessment of results *Ayurvedi*c as well as modern parameters were followed. The result obtained was statistically analyzed and means percentage. SD. SE and 't' value by using the paired 't' test was calculated. The result obtained in this study were as follows-

In this clinical study on Simple developmental Myopia, a total number of 100 patients were registered and were categorized into two groups, comprising of 50 patients in trial group and 50 patients in placebo group. Out of these, 95 patients were completed the whole treatment and 5 patients in Group II were discontinued the treatment against medical advice. (Table no.1) So the observations quoted from here onwards include the data of 95 patients only, who had completed the whole treatment and follow up period.

Patients between the age group of 12 – 25 years were selected for the clinical study. The table no. 02 reveals that majority of the patients (28.42%) were reported in the age group of 18 – 21 years followed by 26.36% in the age group of 15 – 18 years, 25.26% in the age group of 21-25 years, 18.94% in 12-15 years age group.

It is observed from the table no. 03 that there was a female sex group predominance (63.16%) followed by 36.84% male sex group. The table no. 04 reveals that a maximum 31.57% of the patients were Hindus, followed by 22.10% of Muslims, 03.15 % of Christians and 9.47% of other religions.

The table no. 05 illustrates that a maximum 72.63% of the patients were students followed by 12.57% of others, 11.57% of housewives and 04.21% of service persons. From the table no. 06, it is revealed that maximum 42.10% of the patients were having higher secondary education, followed by 28.42% having matriculation, 15.78% having graduation, 08.42% having primary education and 05.26% having post graduation.

From the table no. 07, Out of the 95 patients registered for the present clinical study, 44.21% of the patients were unmarried and 45.26% of the patients were married. The table no. 08 illustrates that maximum number of patients i.e. 40% were belonging to lower middle class followed by 26.31% in poor class, 20% in middle class, 10.52% in upper class and 03.15% of the patients in rich socio-economic class.

The table no. 09 shows that maximum number of patients i.e. 74.73% were vegetarians followed by 25.26% of the patients taking mixed diet. The table no. 10 shows that, maximum number of the patients, i.e. 58.94 % were addicted to tea or coffee, followed by 17.89% patients having no addiction, 16.84% addicted to smoking, 05.26 % addicted to tobacco chewing and 01.05% addicted to alcohol.

It is observed from the table no. 11 that maximum number of patients i.e. 68.42% were having 1 – <4 hours of reading per day followed by 24.21% having 4 – <6 hours reading and 7.36 % having 7 – <9 hours of reading per day. The table no. 12 reveals that a maximum number of patients i.e. 71.57% were having sound sleep followed by 28.42% of the patients having disturbed sleep.

The table no. 13 reveals that maximum number of patients i.e. 83.15% were reported to be of urban habitat followed by 16.48% belonging to rural area. From the table no. 14a, Out of 50 patients with symptom of visual acuity, there was 5 patients got relief from grade 1 to grade 0 after treatment of 90 days while 6 patients have got relief from grade 2 to grade 1 and grade 3 patients have remained unchanged after 90 days of treatment.

From the table no. 14b, Out of 45 patients with symptom of visual acuity, there was no relief in any grade after treatment of 90 days. From the table no. 15a, Out of 50 patients with symptom of headache, there was 14 patients got relief from grade 1 to grade 0 after treatment of 90 days.

From the table no. 15b, Out of 45 patients with symptom of Headache, there were 2 patients have got relief from grade 1 to grade 0 after 90 days of treatment. From the table no. 16a, Out of 50 patients with symptom of eye strain there was 4 patients have got relief from grade 1 to grade 0 while 5 patients have got relief from grade 2 to grade 1 and 9 patients have got grade 3 to grade 2 after 90 days of treatment.

From the table no. 16b, Out of 45 patients with symptom of eye strain there was 3 patients have got relief from grade 1 to grade 0 while grade 2 and grade 3 patients have remained unchanged after 90 days of treatment.

From the table no. 17, The initial mean score in the symptom visual acuity was recorded as 1.5 which is reduced to 1.14 after 90 days therapy. The percentage of relief was observed as 24%. The result was statistically highly significant ($P < 0.001$). The headache was recorded as 0.4, which reduced to 0.12 after 90 days therapy. The percentage of relief was observed as 70%. The result was statistically highly significant ($P<0.001$). The initial mean score of the symptom eyestrain was recorded as 1.52, which reduced to 1.16 after 90 days therapy. The percentage of relief was 24% and the result was statistically highly significant ($P<0.01$).

From the table no. 18a, Out of 50 patients of myopia, there were 15 patients has been cured and 15 patients has been got moderate improvement after treatment of 90 days and 09 patients were got mild improvement while only 11 patients got no improvement after 90 days of treatment. From the table no. 18b, Out of 45 patients of myopia, there were only 03 patients have been mild improvement after 90 days of treatment.

Probable mode of action: - The compound drug *Saptamrita Lauha* contains the drug Haritaki, Vibhitaki, Amaliki, Yashtimadhu, Loha Bhasma, Ghrita and Madhu. The overall effect of the theses drugs is Tridoshshamaka and all are chakshushya. Hence, it disintegrates the pathology of the disease '*Timira*', which is *tridoshaja* in its manifestation.

SUMMERY AND CONCLUSION

As the Myopia is the frequent abundant disease, I decided to do my clinical research work on the Topic ***"A Clinical Study on the Effect of Sampatmrutalauha in the management of Timira, with special reference to Simple Developmental Myopia".*** In my thesis work, the division is made chapter wise, these are Introduction, Literal review, Drug review, Clinical study and at last discussion summery and conclusion have been described on the basis of clinical study.

Total 100 patients of simple developmental myopia were selected and registered according to the selection criteria and divided into two groups. 50 numbers of patients have taken in both groups. In the trial group Saptamrita loha was given while in placebo group Arraroot powder was given. Saptamrita loha was given orally in a dose 500 mg twice with Grita and Madhu daily to the patients of trail group and Arraroot powder was given to the placebo group patient orally in a dose of 500 mg twice daily for 3 months each.

Trail drug Saptamrita Loha was purchased from Dabur Ayurvedic Pharmaceuticals for the clinical study. The contents of drug are Haritaki, Vibhitaki, Amaliki, Yashtimadhu and Loh Bhasma. The trail drug was given to 50 numbers of

patients and the effect was compared with the clinical findings of before and after treatments. Similarly the in placebo drug was given to 50 numbers of patients and the effect was compared with the clinical findings of before and after treatments. Details of clinical study in each individual patient were recorded in the research proforma and observations were made by tabulation and statistical analysis. After statistical analysis all the observations were discussed with reference to the effectiveness and judicious explanations were placed.

Statistical analysis shows that the trial drug is significantly effective to reduce the headache, eye strain and visual acuity with p value (<0.001) but clinically we have observed out of 50 patients of myopia, there were 15 patients has been cured and 09 patients have been got moderate improvement after treatment of 90 days and 15 patients were got mild improvement while only 11 patients were got no improvement after 90 days of treatment while the placebo drug is not significantly reduced the sign and symptoms of simple developmental myopia.

The conclusion of the research work is based on clinical and statistical analysis. It may be proposed that the administration of Saptamrita loha would have been used for a longer period with an increasing dose than the scheduled time, the result might be more effective. Hence it may be concluded that treatment may be longer period with an increasing dose for better result. The present work is not a mile stone in the field of ophthalmology, it emits a small ray of hope for those who are engaged and dedicated for the benefit of Ayurveda particularly for Shalakya tantra. In this aspect further study solemnly invited in order to review the study, which has been omitted due to want of proper scope.

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