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A Clinical Study to Evaluate the Role of Holistic Ayurveda Treatment in Pramehaja Timira w.s.r. Background Diabetic Retinopathy

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Abstract

Diabetic Retinopathy (DR) is a long term complication of Diabetes mellitus. DR is covered under Prameja Timira in Ayurvedic concepts. Taking this concept into consideration an Open randomized control study was conducted with an aim to study DR and Pramehaja Timira conceptually and to evaluate the clinical efficacy of the holistic Ayurvedic approach in Background Diabetic Retinopathy/BDR. Total 30 patients of BDR were divided randomly into two groups, Group A (Treatment group) and Group B (Control group), each having 15 patients (30 eyes). In Group A, classical Virechana karma was adopted followed by Takra shirodhara (21 days), Pratimarsha nasya (30 days) and Rasayana yoga (30 days) simultaneously. In Group B, all the patients were kept under observation for period of 60 days. All patients in both groups continued anti hyperglycemic treatment as prescribed by their physician as well as anti- hypertensive treatment (those suffering from it). The results were drawn after analyzing statistically by paired and unpaired t tests. In Group A, out of 30 eyes, 15 (50.00%) eyes showed mild improvement, 14 (46.67%) eyes showed moderate improvement and one eye (03.33%) was unaffected. No eye showed marked improvement or progression after treatment. In Group B, out of 30 eyes, 25(83.33%) eyes showed mild improvement, three (10%) eyes showed moderate improvement, two (6.67%) eyes showed progression of the disease. No eye got marked improvement. Holistic Ayurvedic treatment was more helpful in relieving signs and symptoms of BDR patients as well as better control of FBS, PPBS and HbA_1C.

Keywords: Pramehaja Timira, Diabetic Retinopathy, Background Diabetic Retinopathy, Holistic Ayurvedic Treatment, Virechana,Takra shirodhara.

Key Messages: Virechana, Takra shirodhara, Pratimarsha nasya and Rasayana yoga use orally are helpful in relieving the signs and symptoms of Background Diabetic Retinopathy.

Introduction

Sedentary life style and enormous amount of stress have created a strong platform for good number of life style disorders including Diabetes Mellitus (DM), which affects almost every system in the body. It is associated with long term complications involving eyes, kidneys, nerves and blood vessels. In eyes Diabetic retinopathy (DR) is one of the major vascular complications of DM. Nearly all people of Insulin dependent Diabetes Mellitus(IDDM) and 75% of Non insulin dependent Diabetes Mellitus (NIDDM) will develop DR after 15 years duration of DM and 18 % will develop DR in less than 15 years duration of DM. India being diabetic capital of world (according to W.H.O.) is feared to end up with an alarming 11.4 million of NIDDM individuals developing DR by 2025. About 20 years ago, DR was 17th cause of blindness & now it has become sixth cause of blindness. As far as the working class or industrial areas are concerned, DR is second leading cause of blindness in working age group (<55 years old) in industrial countries.[1]

Prameha is a disease which is described in almost every Ayurvedic Samhita (literature), having a peculiar feature of prabhuta (excessive) and aavil (dirty) mutrataa (micturation). There is direct reference of ocular complications in Prameha. Netraprakashika a medivial period book by Pujyapaad Muni has direct reference of Netra rogas due to Prameha.[2]

The Etiological factors of *Prameha* are also the causes of *Netra rogas.* Ayurvedic and modern medical sciences agree to the same etiological factors i.e. genetic preponderance, faulty life style like high caloric diet intake & lack of exercise as well as stress. In the pathogenesis of *Prameha, Drava Dhatus* (soft tissues) like *Meda (adipose tissue)*, *Mamsa* (Muscles*)*, *Vasa* (fat*)*, *Lasika* (lymph) etc. get vitiated by *Doshas*. These *Drava Dhatus* cause *Vyana* and *Apana Vata Dushti* in complication stage of *Prameha*, as a result of which there is *Rasayani Daurbalya* (*(*the structural ill health of the vasculature/microcapillaries)[3]in whole body. *Rasayani* are responsible for nourishment of tissues & in microcapillaries abnormlity there is no proper nutrition (Ischaemia/hypoxia) of the tissues, thus many vascular complications may occur in the body like DR.

According to modern science also DM is produced due to improper glucose and fat metabolism in the body. Due to hyperglycemia there are vascular changes like endothelial cell damage, thickening of basement membrane and loss of capillary pericytes, which are responsible for microvascular occlusion and it further leads to formation of microaneurysms, Intra retinal haemorrhages/ IRH and Hard exudates in the retina. In the early phase of DR (Macula is not involved), no treatment is available except wait and watch.

For management of Advanced DR, LASER photocoagulation of leaking vessels is the latest advancement along with medical management with Anti VEGF's and Vitrectomy surgery. All these treatments have their own limitations and complications like excessive retinal tissue damage which hamper the quality of subject's life, macular edema, etc. In *Ayurveda* the treatment of *Prameha* and its complications like *Prameha Pidika* is given in the classical literature on the basis of which a hypothesis is drawn to treat *Pramehaja Timira* / Background Diabetic Retinopathy (BDR) by using holistic *Ayurveda* approach*.*

No such clinical trial on DR in Ayurvedic context using Holistic/complete treatment protocol has been undertaken in any of the *Ayurvedic* PG/research centers so far. So keeping in mind the strong relation between pathogenesis of DR and *Pramehaja Timira* and after analyzing DR in *Ayurvedic* perspectives, this clinical study was conducted.

Hypothesis

Retinal exudation and hemorrhagic features of DR can be considered under *Urdhwaga RaktaPitta*. (extravasation /exudation per supra clavicular area). Hence basic line of treatment of this disease i.e. *Virechana* procedure was adopted to reduce the intra vascular pressure as a whole.

Dharakalpa, a practical classic of *Ayurveda* practiced in south india esp. in Kerela, which is reported to counter eye diseases along with many other local and systemic diseases. As per experience of keraliya physicians, "*Dhatri Takra Shirodhara"* (medicated butter milk sprinkling over the head) has been reported to check the retinal extravasation including hemorrhages. Taking this into consideration,Takra Shirodhara prcedure was adoted in the study.

In DR, vascular pathology involves the pericyte loss and endothelial damage at cellular level. Hence "Rasayana" (Anabolics which prolongs the cell life) seem to check the cellular damage. So a Rasayana consisting of Amlaki, Haridra, Musta, and Guduchi were tried as an oral therapy in the present study. Pratimarsha Nasya which has least contraindications and being an all sense organs nourishing procedure wherein medicated oil is inhaled in the nasal cavity in a very low quantity (2 drops) has also been considered as a trial.

Aims and Objectives

1. To study Diabetic Retinopathy and *Pramehaja Timira* conceptually.
2. To evaluate the clinical efficacy of the adopted holistic approach as per *Ayurveda* in Background Diabetic Retinopathy (BDR).

Ethical Clearance

Study was approved by Institutional Ethics Committee, wide letter no. PGT/7-A/Ethics/2011-12/2087 dated 5/9/2010 S. No. 32.

"CTRI" Registration: This Clinical trial is registered under CTRI (Clinical Trials Registry - India) and is under review stage. (Reference No. REF/013/03/004789)

Materials and Methods

The patients attending the O.P.D. and I.P.D. were selected irrespective of their sex, religion, caste, occupation etc. Patients were diagnosed on the basis of signs and symptoms as per specially prepared proforma wherein direct, indirect opthalmoscopy and colour fundus photography were carried in every patient for diagnosis.

Inclusion Criteria

Patients between age of 40 to 60 years, with history of Type II DM for more than five years, having Background Diabetic Retinopathy (BDR) changes in the eyes and taking oral hypoglycemic drugs as prescribed by their treating physicians were included.

Exclusion Criteria

Patients aged below 40 years and above 60 years, having proliferative and advanced DR changes with early or advanced cataract, glaucoma and taking anti glaucoma treatment were excluded.

Grouping

Selected patients were randomly divided into two groups viz:

Group A - Treated group.

Group B - Control group.

Intervention:

Group A

Virechana

Deepana Pachana – Trikatu [4] (three-seven days)

Snehpana – Triphala Ghrita [5] (three-seven days)

Vashpa Sveda and Bala Taila Abhyanga - three days

Virechana- Virechana Yoga containing Triphala+ Trivrita+ Katuki (two:one:one)

Samsarjana- three- seven days

After Samsarjana following three procedures were done simultaneously -

Takra Shirodhara [6]

containing Amalaki and Takra; for 30 minutes daily for 21 days.

Rasayana Yoga

containing equal amount of Amalaki, Musta, Haridra and Guduchi, Orally five grams twice, two hours before meal with Madhu and Ghrita for 30 days.

Anutaila Pratimarsha Nasya

two drops each nostril daily for 30 days

Group B

Patients were kept under observation for total 60 days.

All patients in both the groups continued with their anti hyperglycemic as well as anti hypertensive therapies during study period.

Follow up: One month.

Assessment Criteria

The assessment was done on the basis of relief found in the cardinal signs and symptoms of the disease adopting scoring, depending upon their severity. (Table- 1& 2).

Laboratory investigations were also done before and after completion of study period.

Assessment of Overall Effect

1. **Cured :** More than 75% relief in the clinical features of patient.
2. **Marked Improvement :** 50 - 75% relief in the clinical features of patient.
3. **Mild Improvement :** 25-50% relief in the clinical features of patient.
4. **Unchanged :** Up to 25% relief in the clinical features of patient.

Observations

Registered and Dropped Out Patient

Total 33 patients(16 in Group A and 17 in Group B) were registered in this study, among them 30 patients (15 patients i.e. 30 eyes in each group) completed the treatment and three patients dropped out due to some family problem. So observations were made on total registered 33 patients and the assessment and results were drawn on 15 patients (i.e. 30 eyes) in each group.

1. Maximum (75.76%) of patients were of age group between 51-60 years, females (60.61%), house wives (57.58%), middle class (78.79 %) and educated up to primary standards (27.27%).
2. Guru dravya (Heavy to digest food articles) was being taken by maximum (78.79%) patients, followed by Madhura rasa (Sweets) (60.6 1%), Snigdha dravya (High protein and fat diet) (54.55%), Ikshu vikara (products of sugarcane) (51.52%), Masha (P. mungo -a pulse) (45.45%), Curd and milk products (36.36%), in their diet. Sedentary life style was found in maximum (90.91%) patients, Diwaswapna (Day sleeping) in 66.67% and Stress in 57.58%.
3. Five to ten years chronicity of DM was present in 54.55% patients whereas chronicity of ocular symptoms was present since five years or less, in 84.85% patients.
4. Hypertension (HTN) was found as an associated disease in maximum (42.42%) patients. (Table-3)
5. Although there are no cardinal symptoms present in DR patients except diminished vision yet the complaints observed among 33 patients in the present study were- Diminished vision (93.75% patients in Group A, 88.23% in Group B) and associated symptoms were- Frequent change in presbyopic glasses / PBG (12.50% in Group A, 5.88% in Group B). Perception of flashes of light (6.25% in Group A, 5.88% in Group B), Floaters (25% in Group A, 5.88% in Group B), Difficulty in dark adaptation/DA (50% in Group A, 23.52% in Group B). (Table-4)
6. The clinical signs observed among 33 patients of both groups were- Microaneurysms/MA (50% patients in Group A,70.58% in Group B), Intra retinal Hemorrhages/IRH (87.50% in Group A,82.35% in Group B),Hard Exudates (62.50% in Group A,76.47% in Group B) (Table-5)

Effect of Therapy

Group A : Treated group

Highly significant result/relief was found in Diminished vision (37.8%), Problem in DA (100%), IRH (18.63%), BCVA(Best corrected visual acuity) (8.40%), FBS (Fasting blood sugar) (26.29%), PPBS (Post prandial blood sugar) (14.89%) and Serum cholesterol (9.80%) ; significant results were found in Frequent change in presbyopic glasses (100%), Floaters (74.90%), MA (30.71%), Hard Exudates (19.36%), Urine sugar(41.65%) and HbA_1C (10.96%) ; no significant results were found in Flashes of light (50.15%) (Table-6)

Group B

Highly significant result/relief was found in Diminished vision (37.8%), BCVA (6.09%), PPBS (14.96%) and Urine sugar (77.73%); significant result/reliefs was observed in FBS (15.24%), HbA_1C (3.84%) and Serum cholesterol (8.44%); no significant results were found in Frequent changes in PBG (100%) , Flashes of light (0.00%), Floaters (0.00%), Problem in DA (0.00%) , MA (3.70%), Exudates (4.25%) and IRH (3.33%). (Table-7)

On comparision between the groups it was found that The Group A (Treatment Group) showed better result in floaters, dark adaptation problem, IRH, FBS and HbA_1C. Group B (Control Group) showed better result in controlling urine sugar. Both the groups showed similar effects on diminished vision, BCVA, PPBS and Serum cholesterol. None of the groups was having significant effect on flashes of light. On comparision no significant differences were found between the groups on frequent change in presbyopic glasses, MA and exudates but individually the Group A had given certainly better results than Group B in these parameters. (Table-8)

Overall Effect of Therapy

In Group A, out of 30 eyes, 14 (46.67%) eyes showed moderate improvement, 15 (50.00%) eyes showed mild improvement and one eye (03.33%) was unaffected. No eye showed marked improvement or progression after treatment.

In Group B, out of 30 eyes, three (10%) eyes showed moderate improvement, 25 (83.33%) eyes showed mild improvement and two (6.67%) eyes showed progression of the diseases. No eye got marked improvement and no eye remained unaffected. (Table-9)

Discussion

1. Maximum patients were of age group between 51-60 years. This is because of the fact that Type-II DM usually occurs after the age of 40 years and the incidence of DR depends upon the chronicity of the DM.
2. Maximum patients were females and house wives, it indicates association of sedentary life style and lack of exercise in them.
3. Maximum patients were belonging to middle class, it may be because they were more prone to stress, which is a risk factor for DR.
4. Maximum patients were educated up to primary standards only. This shows their unawareness towards their health status and irregular checkups for blood sugar and non compliance to the instructions and medicine/treatment.
5. Maximum number of the patients were having following etiological factors -Madhura rasa, Snigdha dravya, Ikshu vikara, Masha, Curd and milk products, Sedentary life style, Diwaswapna and Stress. All above etiological factors clearly reflect the causative factors of Prameha / DM as per classical literature of both health sciences.
6. Maximum patients were having chronicity of DM for five to ten years whereas chronicity of ocular symptoms was present since five or less years in maximum patients. From above points it is clear that symptoms in the eye appear after a long duration of progression of DM.
7. Maximum patients (42.42%) were having HTN as an associated disease which is an additive risk factor for development of DR. It suggests HTN is a risk factor for development of DR.
8. Clinical features like Diminished vision, difficulty in DA, floaters, frequent change in PBG and flashes of light reflect the relation of Prathama and Dwitiya Patalagata Timira.
9. Group A has shown significant effect on floaters. This reflects the reversal of pathology occurring in Prathama and Dwitiya Patalagata Timira on treating with Takra Shirodhara, Nasya and Rasayana Yoga. Inorganic floaters are considered to be due to vitreous liquification and degeneration. This feature is seen in Dwitiya Patala (Uveal tissue with outer retina) pathologies as per Ayurvedic concepts. Thus a holistic approach is having a positive action on health of Second Patala thereby relieving the symptom.
10. Group A has shown highly significant effect on DA problem. Thus it can be concluded that reduction in blood sugar and retinal edema by Takra Shirodhara, Nasya and oral drugs in Group A are potentially increasing the nutritional status of sensory cells of the retina by improving the quality of blood and blood vessels. Thus the quality of Alochaka Pitta / visual pigments is improving and performing its function properly.
11. Group A was more effective in reducing hemorrhages, so it can be said that Group A indicates towards improving health of retinal vasculature in this short duration of treatment with a significant improvement in hemorrhages by reducing the Kleda (abnormal fluidity) of blood and improving the other Dushyas. By virtue of the action of Rasayana Yoga, Takra Shirodhara and Anu Taila; the Rasayani Daurbalya is reduced, that's why no fresh haemorrhages were observed during the study & follow up period.
12. Group A was more effective in lowering FBS reflecting that integrated approach in DM gives a better FBS control. It was also more effective in reducing the level of HbA_1C, reflecting that treatment in group A was helpful in blood sugar control along with its sustained maintenance.
13. Group A individually has shown significant effect on frequent changes in PBG which may be due to the sustained blood sugar control because glycemic fluctuation is mainly responsible for frequent change of PBG. Glycemic control improves the ciliary muscle function as an effect of Takra Shirodhara, Nasya and Rasayana drugs after Virechana in Group A. Muscular tissue gets debilitated due to Kleda which causes Shithilata (Debility) of all Dhatus/ tissues. Holistic approach has reversed this pathology and improved the body muscular tone along with ciliary muscles.
14. Flashes of light occur due to edema causing separation of neurosensory retina from retinal pigment epithelium. In the treatment group mild relief in symptom of flashes of light may be due to reduction in retinal edema to some extent.
15. Similar effects were found on diminished vision, BCVA, PPBS and Serum cholesterol in both the groups, suggesting that there is no additional effect of holistic Ayurveda treatment on these parameters.

Probable mode of Action of Virechana Karma

Prameha is Kapha predominant Tridoshaja Vyadhi, along with vitiation of Rakta Dosha in retinopathy stage because in the pathology of DR, there is leakage from capillaries due to Rakta vitiation. Virechana Karma acts on Tridoshas in general and Pitta and Rakta in particular. Virechana has Pitta Shodhana & Rakta Prasadana property which leads to removal of Kleda from the blood. Due to the Mana Prasadana property it reduces stress & stress related

symptoms; thus Virechana is helpful in breaking the pathologenesis of disease.

Probable Mode of Action of Takra Dhara

Effect of Takra Shirodhara can be understood in the following ways-

1. Procedural effect.
2. Therapeutic effect of medicaments used.

Procedural Effect

The procedural effect of Shirodhara itself seems to produce a relaxation response irrespective of the medicament used. Prameha involves Marmas (vital structures) in its complication phase [7], so Shira Marma (brain) is also involved and as it is Adhisthana (seat) of chakshurendriya (faculty of vision), the procedure satiating Shira Marma can also strenghthen the eye. Antistress activity of Shirodhara has also been noted by many research workers and stress being one of the major factors in DR, Takradhara can be useful in curing the disease.[8]

Probable Mode of Action of Medicaments: Takra (Buttermilk**) and Amalaki** Emblica officinalis)

Takra has Pancha-Rasa except Lavana Rasa, Amla Vipaka, Ushna Veerya properties Due to its Kashaya Rasa, Ushna Veerya, Vikashi and Ruksha Guna, it is useful in pacifying Kapha. Due to Madhura and Amla Rasa and Sandra Guna, it is helpful in pacifying Vata [9], thus being helpful in pacification of Tridoshas.

Moreover Takra (Buttermilk) contains large amount of lactic acid which becomes a good vehicle for trance-dermal absorption of drugs. The efficacy of lactic acid-containing products is linked to their ability to deliver it to specific skin strata.[10] As per Modern science Lactic acid of Takra & active ingratiate of Amalaki may pass through the Stratum corneum into blood vessels and producing desirable effects like anti-inflammatory and antioxidant effects by reaching the target organ.

Probable Mode of action of Anu Taila Pratimarsha Nasya

Anu Taila is an effective formulation which nourishes all the five sense organs. Regular application of Anu Taila into the nostrils improves the perception by the sense organs. Majority of ingredients of Anu Taila shows Tikta Rasa and Laghu Guna properties. [11] These properties are very much in favour of clearing the Srotasas and drying up Kelda, thus helpful in breaking pathogenesis of disease.

Mode of Action of Rasayana Yoga

Rasayana yoga contains four drugs- Amalaki, Guduchi, Musta, Haridra. Probable mode of action of drugs can be understood as follows-

Amalaki (Emblica officinalis)**:** [12,13]

1. Amalaki has Pramehahara (anti diabetic) and Rasayana (rejuvenator) properties.
2. It is rich in antioxidant vitamins; out of which there is rich highly acidic vitamin C content followed by vitamin E. Vitamin C probably by virtue of its powerful antioxidant action reduces the capillary fragility in diabetic retinopathy thus having a definite role in the prevention of fresh hemorrhage episodes and fastening the process of absorption of existing haemorrhages. Vit-C and Vit-E both help in inhibiting platelet aggregation by thromboxane A2 synthesis, thus breaking pathogenesis of DR.

Guduchi (Tinospora cordifolia)

1. It is an efficient rejuvenator (Rasayana)[14] It has immunomodulator, anti inflammatory [15] and anti-stress agent, thus helps in the disease DR.

Musta (Cyperus rotundus Linn):

1. Musta is best pachana dravya [16] thus it acts as a metabolic enhancer in the body. It has protein glycation inhibitory, anti-inflammatory and antioxidant properties.[17] It has superoxide anion scavenging, hydroxyl radical scavenging, nitric oxide scavenging, metal chelating activity, lipid peroxidation inhibition properties.[18]

Haridra (Curcuma longa) [19, 20]

1. Haridra is having Pramehahara and chakshushya properties.
2. Curcumin, a polyphenol; with its antioxidant and anti-inflammatory properties, acts on diabetes-induced oxidative stress and inflammation in the retina. Pro-inflammatory cytokines, tumor necrosis factor-α and vascular endothelial growth factor, which are found elevated in diabetie retinae are prevented by curcumin. Curcumin also prevents the structural degeneration of endothelial cell orgenells and increased capillary basement membrane thickness thus acts on breaking the pathogenesis of DR.

Conclusion

Both the health systems are almost of similar view regarding the aetio-pathology and complications of the Prameha/ DM.

The adopted treatment protocol in the management of DR in this pilot study has proved our hypothesis regarding role of Virechana karma in Urdhwagata Raktapitta, role of Takra Shirodhara in controlling extravasation in the retina, Rasayana Yoga in checking endothelial cell damage and role of Anu Taila as a sense organ nourishing procedure.

It also gives a new insight that integrated approach in the treatment of DM will certainly give better control of the blood sugar, improve the metabolism and delay the complications of DM.

Group A (Treated Group) was more effective than Group B (Control group). Virechana by virtue of its Kleda Harana, Pitta Shodhana, Rakta Prasadana actions; Takra Shirodhara due to its anti stress effect; Anu Taila Pratimarsha Nasya by its microchannels purificating and sense organ rejuvenating properties and all drugs used in Rasayana Yoga by their Chakshushya and Prameha Hara properties have their role in combating the pathogenesis of Pramehaja Timira/DR. Thus by these virtues the holistic *Ayurved*a approach may be helpful in giving an alternate treatment protocol to the DR patients. The results needs a trial for long duration and on larger sample.

Table-1: Subjective Assessment Criteria

Diminished Vision	Grade 0 - No diminished vision. Grade 1 - Dimness in vision but without limitating activities Grade 2 - sometimes difficulty in performing routine work. Grade 3 - Unable to do things independently
Frequent changes in Presbyopic glasses/PBG	Grade 0 - No frequent change in presbyopic number. Grade 1 – Change in presbyopic number every 3-4months Grade 2- Change in presbyopic number every 2 months Grade 3 – Change in presbyopic number every 15-30 days
Floaters	Grade 0 - No perception of floaters. Grade 1- Occasionally interfering with routine work. Grade 2 - Regular interfere with routine work. Grade 3 – Can't perform routine work.
Flashes of light	Grade 0 - No perception of flashes of light Grade 1- Occasionally interfering with routine work. Grade 2 - Regular interfere with routine work. Grade 3 – Can't perform routine work
Dark adaptation/DA Problem	Grade 0 - Adaptation to darkness within few seconds. Grade 1 - Slow dark adaptation with in 10 seconds. Grade 2 - Slower dark adaptation with in 20 seconds. Grade3 - Slowest dark adaptation after 1 minute

Table-2: Objective Assessment Criteria

Micro aneurysms/MA	0 - Absent : No microaneurysms. 1 - Mild : <1/12 of fundus area. 2 - Moderate : 1/12 to <3/12 of fundus area. 3-Severe :3/12 or more (If >4/12 indicate how much)
Intra Retinal Haemorrhage/IRH	0 - Absent : No haemorrhages. 1 - Mild : <1/12 of fundus area 2 - Moderate : 1/12 to <3/12 of fundus area 3 - Severe : 3/12 or more of fundus area (If >4/12 indicate how much)
Hard Exudates	0 - Absent : No Exudates. 1 - Mild : <1/12 of fundus area. 2 - Moderate : 1/12 to <3/12 of fundus area. 3 - Severe : 3/12 or more of fundus area. (If >4/12 indicate how much)
Best Corrected Visual Acuity (Snellen's Distant)	6/6 – 100% 6/9 – 90% 6/12-80% 6/18-60% 6/24-50% 6/36-40% 6/60-20%

Table-3: General observation-wise distribution of 33 patients.

Observation maximum	Number of Patients		Total	Percentage (%)
	Group A(n=16)	Group B(n=17)		
Age (51 – 60 years)	12	13	25	75.76
Sex (Female)	09	11	20	60.61
Occupation (Housewives)	09	10	19	57.58
Economic status (Middle class)	09	11	20	60.61
Education (Primary standards)	06	03	09	27.27
Guru dravya	14	12	26	78.79
Madhur Rasa	09	11	20	60.61
Ikshuvikara	07	10	17	51.52
Masha	10	05	15	45.45
Curd and milk products	07	05	12	36.36
Sedentary life style	14	16	30	90.91
Diwa swapna	14	08	22	66.67
Stress	09	10	19	57.58
Chronicity of DM (5-10yrs)	08	10	18	54.55
Chronicity of symptoms(0– 5 years)	12	16	28	84.85
Associated HTN	06	08	14	42.42

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Table-4 Chief complaints wise distribution of 33 patients

Chief complaints	Number of Patients		Percent (%)	
	Group A(n=16)	Group B(n=17)	Group A	Group B
Diminished vision	15	15	93.75%	88.23%
Frequent change in presbyopic glasses/PBG	02	01	12.50%	05.88%
Perception of flashes of light	01	01	06.25%	05.88%
Floaters	04	01	25.00%	05.88%
Difficulty in dark adaptatation/DA	08	04	50.00%	23.52%

Table-5 Objective finding wise distribution

Objective Findings	Number of Patients		Percent (%)	
	Group A(n=16)	Group B(n=17)	Group A	Group B
Microaneurysms/MA	08	12	50.00%	70.58%
Intra Retinal Haemorrhage/IRH	14	14	87.50%	82.35%
Hard Exudates	10	13	62.50%	76.47%

Table-6 Effect of Therapy in Group A ***n***=30 eyes

Chief complaint	Mean score		Diff	%of diff./ Relief	Paired 't' test				Remarks
	BT	AT			S.D.	S.E.M.	t	P	
Diminished Vision	1.500	0.933	0.567	37.8	0.504	0.0920	6.158	<0.001	HS
Freq change in PBG	0.133	0.000	0.133	100	0.346	0.0631	2.112	<0.05	S
Perception of flashes	0.133	0.0667	0.0667	50.15	0.254	0.0463	1.439	>0.05	NS
Floaters	0.267	0.0667	0.200	74.90	0.407	0.0743	2.693	<0.05	S
Problem for DA	0.733	0.000	0.733	100	0.785	0.143	5.117	<0.001	HS
Micro- Aneurysm	0.433	0.300	0.133	30.71	0.346	0.0631	2.112	<0.05	S
Haemorrhge	1.433	1.167	0.267	18.63	0.450	0.0821	3.247	<0.01	HS
Exudates	1.033	0.833	0.200	19.36	0.484	0.0884	2.262	<0.05	S
C F P	1.933	1.500	0.433	22.40	0.568	0.104	4.176	<0.001	HS
B C V A	79.333	86.000	6.667	8.40	9.589	1.751	3.808	<0.001	HS
FBS	186.067	137.133	48.933	26.29	34.129	8.812	5.553	<0.001	HS
PPBS	260.867	222.00	38.867	14.89	44.670	11.534	3.370	<0.01	HS
HbA_1c	7.787	6.933	0.854	10.96	1.462	0.377	2.262	<0.05	S
S.Cholesterol	220.267	198.667	21.600	9.80	24.885	6.425	3.362	<0.01	HS
U. Sugar	2.00	1.167	0.833	41.65	1.115	0.322	2.590	<0.05	S

Table-7 Effect of Therapy in Group B ***n***=30 eyes

Chief complaint	Mean score		Diff	%	Paired 't' test				Remarks
	BT	AT		of diff	S.D.	S.E.M.	t	p	
Diminished Vision	1.500	0.933	0.567	37.8	0.626	0.114	4.958	<0.001	HS
Freq change in PBG	0.0667	0.000	0.0667	100	0.254	0.0463	1.439	>0.05	NS
Perception of flashes	0.0667	0.0667	0.000	0	0.000	0.000	0.000	>0.05	NS
Floaters	0.133	0.133	0.000	0	0.000	0.000	0.000	>0.05	NS
Problem for DA	0.333	0.333	0.000	0	0.000	0.000	0.000	>0.05	NS
Micro- Aneurysm	0.900	0.867	0.0333	3.7	0.183	0.0333	1.000	>0.05	NS
Haemorrhage	1.000	0.967	0.0333	3.33	0.183	0.0333	1.000	>0.05	NS
Exudates	0.900	0.833	0.0667	4.25	0.254	0.0463	1.439	>0.05	NS
CFP	1.567	1.533	0.0333	2.12	0.414	0.0756	0.441	>0.05	NS
BCVA	82.000	87.000	5.000	6.09	5.085	0.928	5.385	<0.001	HS
FBS	176.667	149.733	26.933	15.24	36.734	9.485	2.840	<0.05	S
PPBS	246.267	209.400	36.867	14.97	47.625	12.297	2.998	0.010	HS
HbA1c	7.619	7.325	0.293	3.84	0.526	0.136	2.161	<0.05	S
S. Cholesterol	229.733	210.333	19.400	8.44	26.254	6.779	2.862	<0.05	S
U. Sugar	2.250	0.500	1.750	77.73	0.886	0.313	5.584	<0.001	HS

Table-8 Comparative Effect of Therapy in Both Groups ***n***=30 eyes in each group

Chief complaints	Percentage relief treatment group	Percentage relief observation group	Unpaired 't' test				
			S.D	S.E.M	t	p	Remarks
Diminished Vision	37.8	37.8	0.504	0.0920	0.000	>0.05	NS
			0.626	0.114			
Frequent changes PBG	100	100	0.346	0.631	0.851	>0.05	NS
			0.254	0.0463			
Flashes	50.15	0	0.254	0.0463	1.439	>0.05	NS
			0.000	0.000			
Floaters	74.90	0	0.407	0.743	2.693	<0.01	HS
			0.000	0.000			
Problem for D.A.	100	0	0.785	0.143	5.117	<0.00	HS

			0.000	0.000		1	
Micro-Aneurysms	30.71	3.7	0.346	0.0631	1.401	>0.05	NS
			0.183	0.0333			
Hemorrhage	18.63	3.33	0.450	0.0821	2.633	<0.05	S
			0.183	0.0333			
Exudates	19.36	4.25	0.458	0.0884	1.336	>0.05	NS
			0.254	0.0463			
C F P	22.40	2.12	0.568	0.104	3.116	<0.01	HS
			0.414	0.0756			
BCVA	8.40	6.09	9.589	1.751	0.841	>0.05	NS
			5.085	0.928			
F BS	8.812	15.24	33.535	6.123	2.446	<0.05	S
			36.095	6.590			
PPBS	11.534	14.97	43.893	8.014	0.171	>0.05	NS
			46.797	8.544			
HbA1C	0.377	3.84	1.437	0.262	2.012	<0.05	S
			0.517	0.0943			
S. Cholestrol	6.425	8.44	24.452	4.464	0.339	>0.05	NS
			25.797	4.710			
Urine Sugar	0.322	77.73	0.802	0.146	0.606	>0.05	NS
			0.900	0.164			

Table-9 Overall effect of therapy in group A and B

Improvement	**Group A**		**Group B**	
	No. of Eyes	**%**	**No. of Eyes**	**%**
Unchanged	01	03.33	00	0.00
Mild Improvement	15	50.00	25	83.33
Moderate Improvement	14	46.67	03	10.00
Marked Improvement	00	0.00	00	0.00
Progression	00	0.00	02	6.67

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