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To study the efficacy of *nisha amalaki yog* in the management of Non proliferative diabetic retinopathy (NPDR). (*Prameha's drushti patal dusti*)

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Abstract

Diabetic retinopathy is emerging problem which can be prevented if diagnosed and treated, so we select the topic, but progress of dieses is still not identical. Lowering of blood glucose and factor responsible fo lowering blood glucose may help to prevent the NPDR thats why *nishaamalky yog* chosen. fundus photography evaluation to assess the result is used to get the adecuate result.

Keyword: NPDR, diabetic retinopathy, *nishaamalaki yog, drushti.*

Introduction:

Worldwide, blindness is one of the greatest fears people have Sedentary life style,Causing diabetes , known as *Prameha*. *Sushruta* explained the eye diseases in "UTTARTANTRA" "*Aupadravikaadhyay*". "Complications" Most are secondary to the complications of primary systemic diseases.(2)

Need of study

Medical treatment of Diabetic Retinopathy is unsatisfactory. However, diabetes must be controlled. Pan retinal photocoagulation (PRP) , to prevent later

stage of Retinopathy, ayurvedic drugs should be evaluate by legal study.(4)

Previous work done –

- **"A clinical study to evaluate the Role of Holistic *Ayurveda* Treatment in *prameha jatimira* w.s.r. Background Diabetic Retinopathy."**

By Priyanka Rani under guidance of K.S.Dhiman

VOL-III , ISSUE-III , JULY-2014 Asian Resonance.

- **"An Appraisal of Clinical Trials in Diabetic Retinopathy".**

By N.Srikant ….CCRAS, New Delhi-58, March 2005

- **"Effect of an *Ayurvedic* Compound drug (*triphala guggulu*) in Diabetic Retinopathy".**

By A.K.Singh, M.Sahu and N.Srikant ……Dept. CCRAS.Deptt. Of Shalya-shalakyabhu ,Deptt of Ophthalmology ……JRAS VOL-22 No. 3-4(2001).

"A Comparative Clinical Study ofhypoglycaemic effect of nishaamalaki and khadirkramuka".

By Dr.K.R. Sharadamani Guide- Dr. V.G Neginhal.

Aim :-"the pilot study to evaluate the clinical efficacy of the nisha amalaki yog in non proliferative diabetic retinopathy."

Objective:

"to make a comprehensive compilation on retinopathy according to ayurveda & modern."

To study the progress of NPDR clinicaly subjective and objective parameters in natural course of disese.

Study design:

A prospective Single blind randomize Control clinical trial will be performed as follows

1) STUDY CENTER: 30 patient fulfilling the criteria and attending the OPD/IPD of the *Shalakya* Department and Hospital of the *Vidarbh Ayuved Mahavidyalaya & Gopalnanaji* Tank Hospital will be selected for the present study irrespective of age, sex, religion, etc.

2) SAMPLE SIZE:

30 patient excluding the dropped out will be recruited after satisfying inclusion & exclusion criteria.

MATERIALS AND METHODS

A) CONCEPTUAL STUDY DESIGN

B) PHARMACEUTICAL STUDY DESIGN

Study groups : Both the groups were advised to continue

thereantihypoglycemic drug as prescribed by MD Physician.

Group A **--15** patients of Trial group were given *Nisha-Amalaki yoga* for **8** months,

Group B **--15** patients were treated with Placebo group for 8 month

According to American academy of ophthalmology and Other Studies Stated that Management line for NPDR is optimum control of blood glucose. Hence for group B, Placebo was given means no extra medicine was given with Anti hypoglycemic drug as prescribed by his MD physician .(3)

C) CLINICAL STUDY DESIGN

INCLUSIVE CRITERIA:

1) Patient with Type 1 and type 2 Diabetes Mellitus.

2) Having Non proliferative Diabetic Retinopathy in the eyes.(If the selected NPDR patient has NPDR in one eye than Both the eyes are selected for study because other eye may develop pathology in other eye)

3) Taking oral hypoglycaemic drugs as prescribed by their treating Physician were included.

4) Patient who are mentally fit.

EXCLUSION CRITERIA:

1) Proliferative Diabetic Retinopathy.

2) Patient having serious systemic illness like Malignancy, Neuphropathy or Patient on Dialysis, Hypersensitivity, etc.

3) Pregnancy

4) Eye having opacity that obstructs the field of view in examination of retina like central corneal opacity, cataract, any vitreous opacity etc.

RANDOMIZATION

Patients were Given *Nisha-amalakiyog* as per Lottery method of randomization

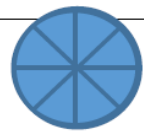
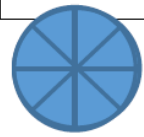
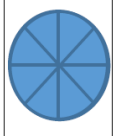
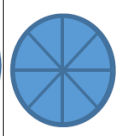
INTERVENTION OF CONTROL & TRIAL DRUGS:

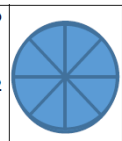
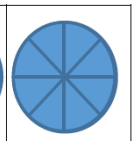
Group-A: will be Intervened with nishaaamalaki Yoga with maximum tolerance dose (According to sharangdharsamhita 6) of 6gm bid, for 8 month & The observation will be taken every monthly.

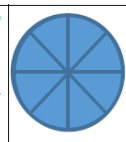
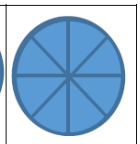
Group-B: Will be intervened with only placebo.

CRITERIA FOR ASSESSMENT(12)(13)

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	Scores = 0 1 2 3
False 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	0 1 2 3
Diminution of vision	No error of refraction 6/6 Mild -6/9 to 6/24 Moderate-6/24 to 3/60 Severe – 3/60 to counting finger 1meter	0 1 2 3

ASSESS	GRADE	RIGHT EYE	LEFT EYE
1, MICRO ANEURYSM	**0** - Absent : No microaneurysms. **1** - <1/12 of fundus area. **2** - 1/12 to <3/12 of fundus area. **3**- 3/12 to 6/12 fundus area 4- >6/12 fundus area		
2, INTRA RETINAL HEMORRHAGE	**0** - Absent : No hemorrhages. **1** - : <1/12 of fundus area **2** - 1/12 to <3/12 of fundus area **3** - 3/12 to 6/12 fundus area **4** - >6/12 fundus area		

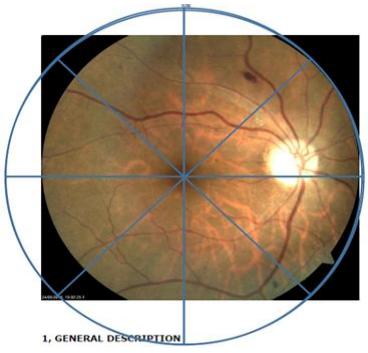
3, EXUDATES	**0** - Absent : No Exudates. **1** - Mild : <1/12 of fundus area. **2** - Moderate : 1/12 to <3/12 of fundus area. **3** - Severe : 3/12 to 6/12 of fundus area **4** - >6/12 fundus area		

4, VENOUS BEADING	**0** - Absent : No Venous beading **1** - Mild : <1/12 of fundus area. **2** - Moderate : 1/12 to <3/12 of fundus area. **3** - Severe : 3/12 to 6/12 of fundus area **4** - >6/12 fundus area		

OBSERVATIONS AND RESULT

Selection of grading in fundus photograph by making 8 parts of circle of fundus having center at the macula.

For example:



1, GENERAL DESCRIPTION

□ □ Incidence of DR

DM	No. Of DM patients	Diabetic Retinopathic patients	Percentage
Type 2 DM	101	33	32.67 %
Type 1 DM	4	1	25.00 %
Total	105	34	32.38 %

Table No 1 Table showing Incidence of DR in IDDM and in NIDDM patients

In present research study, 34 DR patients were selected for study out of 105DM patients. In which 33 patients were diagnosed as Diabetic retinopathy from 101 type 2 DM patients and one was diagnosed out of 4 type 1 DM patients. But DR from Type 1 Diabetes were non inclusive for present study Hence 33 DR from Type 2 DM were selected for study.

EFFECT OF THERAPY ON CLINICAL PARAMETERS

GRADE system, Each of symptoms and the parameters was assessed before the start of treatment and after the end of treatment period.

Within Group Analysis

Tests used - for within group analysis , paired 't' test was applied to analyze objective parameter and biochemical parameters and

Unpaired t test was used to analyze data of comparison between the group .

TABLE OF EFFECT OF THERAPY IN GROUP A n= 25 EYES

Chief complaints	Mean score		Diff	f diff/ R	paired 't' test				Remarks
	BT	AT			S.D (BT/ AT)	S.E.M (BT/ AT	t	p	
DOV	1.44	1.48	-0.04	-2.77	0.5831/0.6532	0.1166/0.1306	1	0.3773	NS
perception of false flashes of light	0	0	0	0	0	0	0	0	
Floaters	0	0	0	0	0	0	0	0	
Microaneurysms	1.72	1.64	0.08	4.65	1.061 /1.114	0.2123/0.2227	0.6247	0.5381	NS
Haemorrhages	1.2	0.96	0.24	20	1.384/1.136	0.2769/0.2272	1.186	0.2471	NS
Exudates	0.6	0.64	-0.04	-6.66	1.190/1.221	0.2380/0.2441	1	0.3273	NS
Venous beading	0.12	0.16	-0.04	-33.33	0.3317/0.4726	0.066/0.0945	1	0.3273	NS
ABG	207.9	206.1	1.8	0.865	52.05/162.94	13.44/16.25	0.1407	0.8901	NS
HbA1C	8.873	8.815	0.058	0.653	1.813/2.195	0.4681/0.5669	0.1315	0.8972	NS
S.chol	203.9	177.5	26.4	12.094	55.43/41.35	14.31/10.68	3.423	0.0041	S
S.creat	1.091	1.069	0.022	2.016	0.2947/0.1258	0.076/0.03248	0.3044	0.7553	NS
F	121.7	141.2	-19.5	-16.02	45.25/68.74	11.68/17.75	1.189	0.254	NS
PP	165..3	193.3	-28	-16.94	59.71/106.8	15.42/27.59	1.065	0.305	NS
Urin sugar	0.2	0.2667	-0.066	-33.33	0.5606/0.5936	1.447/0.1533	0.3669	0.7192	NS

TABLE OF PLACEBO GROUP B n=28 EYES

Chief complaints	Mean score		Diff	of diff/Rel	Paired 't' test				Remarks
	BT	AT			S.D.	S.E.M	t	p	
DOV	1.536	1.536	0	0	0.6929/0.7927	0.1310/0.1498	0	1	NS
Perception of flashes	0	0	0	0	0	0	0	0	0
Floaters	0	0	0	0	0	0	0	0	0
Microaneurysms	2.429	2.357	0.072	2.964	1.168/1.224	0.2208/0.2313	0.5704	0.5732	NS
Haemarrhages	1.75	1.786	-0.36	-2.05	1.295/1.197	0.2447/0.2263	0.1825	0.8566	NS
Exudates	1	1	0	0	1.36/1.33	0.2272/0.2520	0	1	NS
Venous beading	0.25	0.2857	-0.0357	-14.28	0.4410/0.5345	0.0833/0.1010	1	0.3262	NS
ABG	194.3	193.4	0.9	0.463	30.59/48.43	7.899/12.5	0.08448	0.9339	NS
HbA1C	8.407	8.373	0.034	3.4	1.065/1.685	0.4681/0.2751	0.8264	0.9353	NS
S.chol	164.9	157.1	7.8	4.7	24.3/25.76	6.275/6.651	0.9858	0.341	NS
S.creat	1.067	1.077	-0.01	-0.937	0.2619/0.1793	0.06763/0.04631	0.1197	0.9064	NS
FBS	163.4	125.7	37.7	23.07	72.71/32.13	18.77/8.297	2.231	0.0426	*
PP	210	152	58	27.61	89.83/46.38	23.19/11.98	2.407	0.0305	*
urin sugar	0.8	0.133	0.667	75.79	1.265/0.5164	0.3266/0.133	2.092	0.0522	NS

DISCUSSION

POINTS

The pilot study reveal that

1, The incidence of DR detected in 34 patients out of 105 DM patients. Means 32.38% patients had Diabetic Retinopathy.

2, The incidence of DR in Type 1 DM was 25% but due to small data of Type 1 DM we can't tell about the actual % of incidence.

According to selection criteria Type 2 DM taken for clinical study.

3, The incidence of DR in Type 2 DM was 32.67% hence we can say DR is not a rare complication in DM patients.

4, Maximum patients in the present study belonged to the age group between 50-59 years. It may be due to occurrence of DM is seen after 40 and to develop micro vascular retinal changes chronicity of DM is required.

5, More than 50 % patients had no family history of DM ,in this % of patients diet and sedentary life style stress plays important role and more than 40 % patients had family history of Diabetes.In these genetic factors plays important role to develop DM.

6, More than 60% patients had dominancy of *Kaphadosha* which is main and basic pathogenic factor to develop *Prameha*.

7, Maximum patients had mental stress related to socioeconomic burden from their children. With the time generally it's found that children s avoid to spend money for their daily medication. Because of this patients are always in negative thinking attitude.

8, 90% patients have disturbance in sleep due to urine call in mid night and negative thinking which ultimately lead to poor digestion and enhance further metabolic illness.

9, 33.33% have hypertension which gives beneficial role to further micro vascular changes/ complication in retina like hemorrhage, arterial abnormality etc.

10, More than 70 % patients in present study have duration of known to DM is less than 10 years and it may be because in our OPD we don't have that level of infrastructure and retinologist hence most of the patient came in our OPD with no symptoms which were referred by another OPD like *Kyachikitsa, Shalya* etc. and symptomatic patient came which has only some presbyopic low vision and which could be easily corrected by lens hence most of the people who visited to hospital they all were knowing about lack of facilities. Hence only the working people and newly detected (<10 yrs)DM who required presbyopic correction only they visited our OPD.

11, All the patients in present study have hba1c level of more than 6% means more than normal limit and this abnormal level of glycosylated hemoglobin is the main cause of pathogenesis of Retinopathy in Diabetic patients.

12, Another most common complication of DM is sugar cataract which is early developed due to uncontrolled blood sugar level. In present study 19 eyes out of 60 had developed cataract and 13 were operated and pseudophakic and 7 eyes had cataract which are excluded from study due to its opacity fundus examination is obstructed.

13, One patient showed Asteroid hylosis in one eye the cause of this condition is poorly known but it may be due to diabetes as explained earlier.

14, In my present study floater and false flashes of light was not seen in any patient may be because this symptoms is seen when any opacity occur in vitreous due to hemorrhage in PDR and flashes are seen when Posterior vitreous detachment occur but in NPDR no such symptom develops still I included that point in my study just to correlate *Drishtipatalagata dosh dushti* .and DOV which is a common eye problem can be found even in Non DM patients and which indicate that 4^{th} *patala gat dosh dushti* symptom is only DOV. And Floters and flashes are not the symptoms of 4^{th} *patal gat dosh dushti.*

15, Almost in fundus of every patient, micro aneurysm is found because it is the typical features of NPDR .

16, Intra retinal hemorrhages also found in more than than 60% of eyes. These hemorrhages ere the later stage of micro aneurysms. Exudates are present in 37% because it occur in later stage and in

hiperlipidaemic condition. Venous changes are present in the later stage of complication of DR. 17% eyes showed this changes,.

17, Group A has shown Non Significant effect on DOV.

Conclusion:

The adopted treatment protocol in the management of DR in this pilot study has disproved our hypothesis regarding role of *Nish-Amalaki* in Non Proliferative Diabetic Retinopathy in 8 month duration. Further study must be done on the same drug in long duration or with *shodhana* process.

Both the groups have similar result on subjective and objective criteria. This small scale study shows correlation between anatomy of innermost *drishtipatala* with retina in matter of its transparency, thickness (600micron) and position. Unless pre retinal hemorrhage doesn't occur development of floaters cannot be seen. It indicates that there is opacity in vitreous cavity. According to *sushruta* floaters are the symptom of *medo patalagata doshadushti* and development of floaters by pre retinal hemorrhage in PDR case means till patient does not shows any visual symptoms

. Pathology of Diabetic Retinopathy is the micro vascular complication of Diabetes which was proven by *sushruta in samhita* that all the eye disease produces in eye by *doshas* travelling upper body via blood vessels.

Hence from above study we can concluded that **retina is the** 4^{th} ***patal*** of eye.

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ABBREVIATIONS

- DM- Diabetes Mellitus
- DR- Diabetic Retinopathy
- NPDR-Non Proliferative Diabetic Retinopathy
- PDR-Proliferative Diabetic 4Retinopathy
- NIDDM- Non Insulin Dependent Diabetes Mellitus
- IDDM-Insulin Dependent Diabetes Mellitus
- PRP- Pan Retinal Photocoagulation
- AGE's- Advanced Glycosylated End products
- ETDRS- Early Treatment of Diabetic Retinopathy study
- OCT- Optical Coherence Tomography

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