

A STUDY ON EFFECT OF MUSTADI SHIROLEPA IN DIABETIC RETINOPATHY

Mariswami¹, Ahalya S²

¹PG Scholar, Dept of PG Studies in Shalakyta Tantra.

²Professor & Principal, Government Ayurveda Medical College, Bengaluru-560009, Karnataka, India

Email: mariswami007@gmail.com

ABSTRACT

Background: Diabetic retinopathy (DR) is a leading cause of acquired vision loss in middle-aged and elderly people globally. In modern science, other than the meticulous control of diabetes there is no proven non-invasive management for the prevention or cure of diabetic retinopathy. In *Ayurveda*, there is no direct reference for Diabetic Retinopathy. Based on pathological changes diabetic retinopathy can be correlated with *Kaphaja Raktapitta* or *Urdhwaga Raktapitta*. The dominance of *Bahu Drava Shleshma* greatly disturbs *Alochaka Pitta* by increasing its *Dravatwa*. This *Samprapti* results in *Kaphaja Raktapitta* or *Urdhwaga Raktapitta* ^(A.H.Ni.3/7) Acc. to *Acharya Pujoyapada muni*, *netra roga* can also manifest as an *Upadrava of Granthi* and *Meharoga*. *Tuvaarakadi Anjana* gives the clue regarding *Netra Upadrava* due to *Prameha Roga* in *Madhumeha chikitsa*. ^(Su.Chi.13/35) Hence in present study an effort is made to observe the effect of *Shirolepa* through *Mustadi Churna* in Diabetic Retinopathy. **Objectives:** To evaluate the efficacy of “*MUSTADI SHIROLEPA*” in the management of Diabetic Retinopathy. **Methods:** A clinical study was conducted with a trial group having 30 patients (Single group) for a period of 35 days (3 sittings of 7 days with a gap of 7 days each) with procedure of *Mustadi Shirolepa*. These patients were randomly selected irrespective of gender and they were advised not to withdraw from regular diabetic medications and they were monitored regularly for good glycaemic control. **Results:** After the treatment it was observed that there was statistically significant result in the main signs and symptoms i.e. blurring of vision, floaters, microaneurysms, haemorrhages, exudates and visual acuity for distant and near vision. Out of 30 patients in this study, 2 patients (7%) were getting No Improvement, 25 patients (83%) were getting Mild improvement, and 3 patients (10%) were getting Moderate improvement.

Keywords: Diabetic Retinopathy, *Mustadi Shirolepa*, Diffusion mechanism, Microcirculation.

INTRODUCTION

Diabetic retinopathy is a highly specific vascular complication of both Type 1 and Type 2 Diabetic Mellitus with approximately 8% of legally blind individuals are reported to have Diabetic Mellitus and approximately 12% of new blindness is due to Diabetic retinopathy in India. An estimated 31.7

million population have Diabetic Mellitus as per WHO, 2 Millions in Bangalore itself. 10% of Diabetic population have Type 1 (Insulin Dependent DM) which is diagnosed within 40 years of age¹. Majority of Diabetic patients have Type 2 (Non- Insulin Dependent DM) diagnosed later than 40 years of age.

If 17.6% have Diabetic Retinopathy, this would translate to more than 5.6 million subjects with Diabetic Retinopathy.¹

Although at present, there are no known means to prevent these conditions, laser surgery and other surgical modalities such as vitrectomy are most effective when initiated at the time a person approaches or just reaches high risk proliferative diabetic retinopathy or before visual acuity is lost from diabetic macular edema. But, this cannot restore the vision that as already been lost.

In *Ayurveda*, there is no direct reference for Diabetic Retinopathy. Based on pathological changes diabetic retinopathy can be correlated with *Kaphaja Raktapitta* or *Urdhwaga Raktapitta*. The dominance of *Bahu Drava Shleshma* greatly disturbs *Alochaka Pitta* by increasing its *Dravatwa*. This *Samprapti* results in *Kaphaja Raktapitta* or *Urdhwaga Raktapitta* (A.H.Ni.3/7) *Pujyapada Muni* has written *Netra Prakashika* which belongs to 6-7th century A.D. The book exclusively explains 100 *Netra Rogas* and treatments². While explaining cause of eye diseases,

ग्रन्थिमेहादिरोगैश्च कृत्रिमैरभिचारतः |

Netra roga can also manifest as a complication of *Granthi* and *Meharoga*.²

Tuvaarakadi Anjana gives the clue regarding *Netra Upadrava due to Prameha Roga in Madhumeha chikitsa*. (Su.Chi.13/35)

The changes in blood vessels of retina can be understood by the concept of *Srotodusti* as follows;

1. *Ati pravritti* - Neo vascularization
2. *Sanga* - Retinal vein or artery occlusion
3. *Vimarga gamana* - Exudates in retina
4. *Sira granti* - Micro aneurysms

Takradhara is proved to be effective in *Madhumeha* and its complications.³ Procedure of *Shirolepa* which is also said to have equal effect of *Takradhara* has been taken up for the study since it has got few merits over *Dhara* like:

- Less intervention in manual support.
- Cost effective since no major infrastructure is required.
- Adoptable at clinical level.

Hence in present study an effort is made to observe the effect of *Shirolepa* through *Mustadi Churn*⁴ in Diabetic Retinopathy.

Materials and methods

The patients were selected from the OPD & IPD of Sri Jayachamarajendra Institute of Indian Medicine, Bangalore- 09 with features of Diabetic Retinopathy.

Selection of patients

30 patients diagnosed as Non-Proliferative Diabetic Retinopathy of either sex will be randomly selected.

Inclusion criteria

All patients presenting with signs and symptoms of NPDR (Non-Proliferative Diabetic Retinopathy) were taken into this study.

Symptoms: Blurred vision, fluctuating vision, sudden loss of vision, floating spots.

Sign⁵: Micro aneurysm, retinal haemorrhages, hard exudates, cotton wool spots, intra retinal micro vascular abnormalities, dot and blot haemorrhages.

2. Age group between 20-80years.

3. Patients with good glycaemic control- In diabetic patient - HbA1C <7.5%

Exclusion criteria:

1. Patient with Proliferative Diabetic Retinopathy.
2. Patients with other advanced diabetic eye conditions.
3. Juvenile diabetes.
4. Other types of vascular retinopathies like hypertensive retinopathy, retinopathies of blood dyscrasias (decrease or increase in red blood cells number or size), gestational diabetic retinopathy, retinopathy of prematurity, sickle cell retinopathy is excluded.
5. Patient with uncontrolled diabetic mellitus- HbA1C >7.5%

Diagnosis:

1. Based on clinical history given by the patient.
2. Visual acuity
3. Direct ophthalmoscope

Trial drug

Mustadi Churna⁴: *Musta*, *Haritaki*, *Vibhitaki*, *Amalaki*, *Haridra*, *Devadaru*, *Moorva*, *Aindri* (*Indravaruni*), *Lodratvak Churna*. This *Churna* is said to

be *Sarva Prameha hara* and used in *Mutrakruccha* disorders.

Mustadi Shirolepa: *Mustadi churna* mixed with *Takra* and triturated well to form a fine paste which is used for *Shirolepa*.

Thickness of one *Angula Shirolepa* is applied.

Before and after procedure *Shiroabhyanga* will be done with *Asanabilwadi Taila*.

Study Design:

30 patients suffering from Non-Proliferative Diabetic Retinopathy will be taken for study. These patients will be advised not to withdraw from regular diabetic medications and monitored regularly for good glycaemic control.

Table 1:

Group	Chikitsa	Prayogakaala	Prayogaavadhi	Follow up period
1.	<i>Mustadi Shirolepa</i>	Morning	45 minutes daily for 7 days with gap of 1 week for 3 sitting.	30 days (once in forth night)

Assessment criteria:

Assessment was done on the basis of clinical observation (subjective and objective) before and after - treatment. The result obtained shall be statistically analysed and conclusions shall be drawn.

Parameters:

Subjective Parameters:

1. Blurred/ distorted /fluctuating vision.
2. Floaters.

Objective Parameters:

1. Fundal photography
2. Visual acuity.

Hemorrhages and IRMA	0- Absent: No Haemorrhages/ IRMA 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.
----------------------	---

Table 3:

Best Corrected Vis-ual Acuity (Snellen’s – Distant and Jaeger’s- Near vision)	0-6/6	100%	N6	100%
	1-6/9	90%	N8	80%
	2-6/12	80%	N10	60%
	3-6/18	70%	N12	40%
	4-6/24	60%	N18	20%
	5-6/36	50%	N24	5%
	6-6/60-4/60	40-20%	N36	<5%
7-3/60 or less	<10%			
Color Fundus Pho-tograph (Grading as per ETDRS classifica-tion)	No retinopathy 1-Mild NPDR 2-Moderate NPDR Severe to very severe NPDR			

Table 2: Gradation Index (Taken from scales of National screening committee)

Blurred Vision	0-Absent 1-Mild with static or improving 2- Moderate with progressive 3-Severe with steadily worsening
Floaters	0-Absent 1-Mild floaters (2-3dots /thread) 2-Moderate floaters(4-8dots/threads) 3-Sever Floaters (>8 dots /threads)
Micro aneurysms	0-Absent: No Micro aneurysms 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
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.

Observations

Demographic data:

In the present study, maximum patients were in age group of 51-60 years (33%), were males 21(70%), 24(80%) were from middle class.

Data related to disease:

Maximum number of patients were suffering from Type 2 Diabetic mellitus 29 (96.6%), followed by duration of DM in between 11-15 years 11(36.6%), 4 (13.3%) patients undergone laser surgery, both eyes are affected 25 (83.3%) patients, followed by blurring of vision 30 (100%) patients, floaters 7 (23.3%), mi-

cro aneurysms 23(76.6%), hemorrhages 24 (80%), exudates 10 (33.3%), IRMA (Intra Retinal Micro vascular Abnormalities) changes were not seen in patients, 14 (46.6%) patients were moderate NPDR. The incidence of clinical signs and symptoms are depicted in chart No.1.

Results

In right eye;

In **subjective parameters** like blurring of vision percentage of relief was 37.4%, statistically significant (P <0.05), in floaters, percentage of relief were 51.51%, and in micro aneurysms the relief observed was 40.70%, which were statistically significant (P <0.05), in the hemorrhages and exudates the relief percentage observed were 39.09% and 14.4% respectively.

In **objective parameters** like visual acuity – for distant vision percent of relief was 31.90%, statistically

significant (P <0.05), and in near vision percentage of relief was 43.48%, which were statistically significant (P <0.05).

In left eye;

In **subjective parameters** like blurring of vision percentage of relief was 30%, statistically significant (P <0.05), in floaters, percentage of relief were 51.85%, and in micro aneurysms the relief observed was 44.66%, which were statistically significant (P <0.05), in the hemorrhages and exudates the relief percentage observed were 44.66% and 17.5% respectively.

In **objective parameters** like visual acuity – for distant vision percent of relief was 34.44%, statistically significant (P <0.05), and in near vision percentage of relief was 31.71%, which were statistically significant (P <0.05) (Table No. 4 & 5).

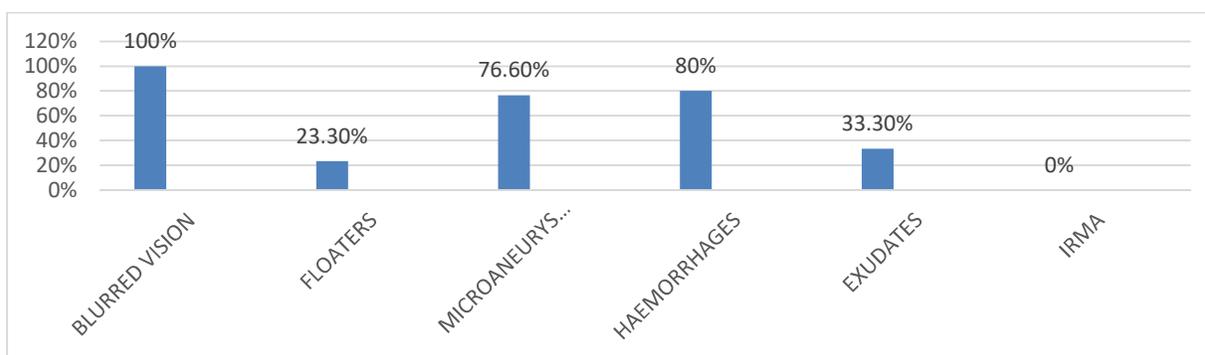


Chart I: Incidence of parameters to assess Diabetic Retinopathy.

After completion of the treatment, results were sustained for a long time in trail group patients who came

for follow-up. No adverse effects of the therapy came into light during or after the course of the trail.

Table 4: Effect of improvement in subjective parameter

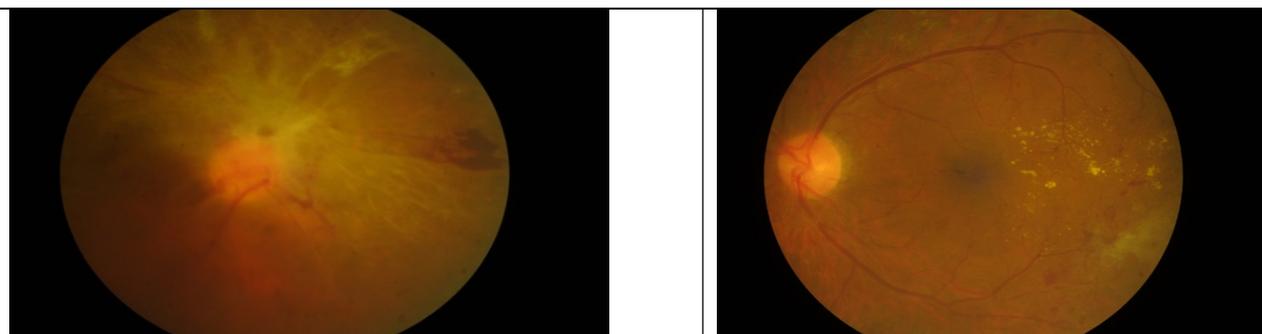
Right eye					
Parameters	BT	AT	%	t value	p value
1)Blurring of vision	1.80	1.33	37.04	3.46	<0.05
2)Floaters	0.33	0.17	51.51	1.13	<0.05
Left eye					
1)Blurring of vision	1.33	0.93	30	2.29	<0.05
2)Floaters	0.27	0.14	51.85	1.68	<0.05

Table 5: Effect of improvement in objective parameter

Right eye					
Objective parameters	BT	AT	%	t value	p value
1)Micro aneurysms	1.13	0.67	40.70	2.64	<0.05
2)Haemorrhages	1.10	0.67	39.09	2.64	<0.05
3)Exudates	0.50	0.43	14.4	0.33	<0.05
4)Visual acuity –					
Distant vision	3.87	2.63	31.90	2.72	<0.05
Near vision	0.77	0.43	43.48	2.16	<0.05
Left eye					
Objective parameters	BT	AT	%	t value	p value
1) Micro aneurysms	1.03	0.57	44.66	3.21	<0.05
2) Haemorrhages	1.03	0.57	44.66	3.21	<0.05
3) Exudates	0.40	0.33	17.5	0.37	<0.05
4) Visual acuity					
Distant vision	3.00	1.97	34.44	2.55	<0.05
Near vision	2.73	1.87	31.71	2.25	<0.05

FUNDAL PHOTOGRAPHY

BEFORE TREATMENT



AFTER TREATMENT

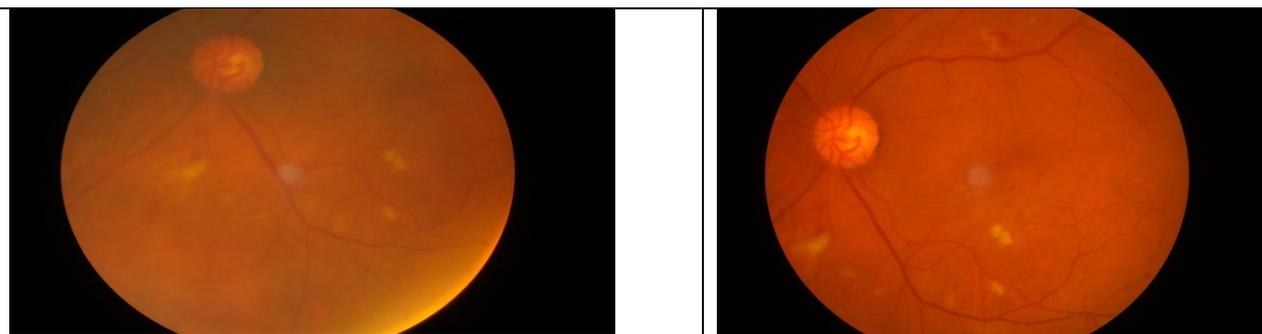
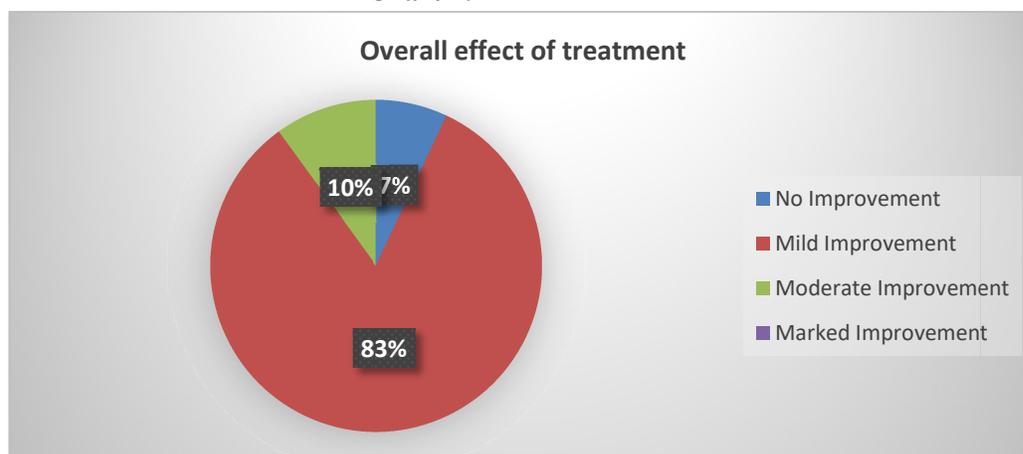


Chart 2: Overall effect of treatment

In Overall effect of treatment in NPDR, out of 30 patients in this study, 2 patients (7%) were getting No Improvement, 25 patients (83%) were getting Mild improvement, 3 patients (10%) were getting Moderate improvement.

Overall effect of the treatment is 48.14%.

DISCUSSION

DR is the most common ophthalmic complication of diabetes mellitus occurring in the patients of chronic and uncontrolled DM. Recently the prevalence of Diabetic Retinopathy is raising among the diabetic population. The conventional therapies available for retinopathy are LASER, Anti-VEGF injections. These help in arresting the progression of the disease for a period of time. These are invasive requiring frequent intra ocular injection and therapeutic agents are extremely expensive. Due to complexity of angiogenic single agent therapy is insufficient in some patients. The recurrence of condition is often observed. So, the present modern line of management is not fully satisfactory in preventing and improving the condition of the disease.

Shirolepa is a unique method of medicinal application which is widely practiced in traditional *Ayurvedic* practice in *Kerala*; it is basically a sort of external application of medicine. So far, many research works have been undertaken to evaluate the efficacy of *Takradhara* on diabetic retinopathy and proved to be effective.³

Drugs are *Musta*, *Haritaki*, *Vibhitaki*, *Amalaki*, *Haridra*, *Devadaru*, *Aindri (Indravaruni)*, *Moorva*, *Lodhra tvak*. These drugs are *Kapha-pitta hara*, *Prameha hara*, *Cakshashya*, *Rasayana* and *Anulomana*. It helps in relieving *Srotodusti*.

With the help of postulated theory and research works, hypothesis for the action of *Shirolepa* can be substantiated as below⁶:

1. Lipophilicity of a drug is a main factor for skin permeability. Lipophilic binary vehicle would be a good vehicle to carry hydrophilic drugs. So, the oil used for *Abhyanga* is lipophilic in nature which would act as a vehicle to carry the hydrophilic drugs.
2. Hydration of skin, degree of friction to the surface and increase in local temperature can be achieved by doing *Abhyanga* as *Purva karma*. It also aids for vasodilatation and easy penetration of drug through the skin.
3. Concentration of drug is achieved when the medicine is mixed with *Takra* and paste is prepared from it. This helps for better absorption.
4. After application of warm medicinal paste, covering it with banana leaf would help to maintain the temperature and also prevent loss of heat which aids for faster absorption.
5. Penetration of active ingredients through follicles and skin has helped to reverse the pathology. Hence *Abyanga* done here as *Purva karma* for *Shirolepa* forms a lipophilic surface and it also stimulates the ophthalmic nerve and the medicinal

lepa applied to the scalp might have entered the microcirculation of ophthalmic artery thus reaching the target organ by process of passive diffusion and desired effects are achieved.

CONCLUSION

Owing to the problems and adverse effects of different medicament, photocoagulation and vitrectomy employed to manage DR, it is imperative to explore a potent *Ayurvedic* procedure with drugs having both *Kapha pittahara* and *Prameha hara* properties which could tackle effectively this problem at biological level without adverse effects; hence this study was taken up. The study was aimed at finding out the efficacy of *Shirolepa* procedure in managing NPDR.

REFERENCES

1. <https://www.ncbi.nlm.nih.gov>article> Ryan Lee, Epidemiology of diabetic retinopathy, diabetic macular edema and related vision loss.
2. Nandikeshwara. Netra Prakashika. English Translator. Udaya Shankar, Edition 1st.Varanasi: Chaukambha Vishvabharati. 2013. Chapter 4/8. pp31.
3. Sahasrayoga – edited by Vaidhya Mahendra Singh Arya. New Delhi; Kendriya Ayurveda Evam Siddha Anusandhana Parishad; 1990.621 pp.
4. Kaviraj Govind Das Sen; Bhaishajya Ratnavali; Siddhiprada Hindi commentary ed; by Prof. Siddhi Nandan Mishra. Chaukamba Surbharati Prakashan Varanasi: 2005.vol II. cha 37; p 1196.
5. Khurana AK, Khurana B. Comprehensive Ophthalmology. 6th ed. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd: 2015; p 275.
6. <https://en.m.wikipedia.org> – Absorption (Skin).
7. Sushruta. Sushruta Samhita with the Nibandha Sangraha Commentary of Sri Dalhanacharya and the Nyayachandrika Panjika of Sri Gayadasacharya on Nidanasthana. Edited by Vaidya Jadavji Trikamji Acharya and Narayan ram Acharya ‘Kavyatirtha’ 1st ed. Varanasi: Chaukambha surabharati prakashana; 2008. 824 pp.
8. Vagbhata. Astnga Hridayam – with commentaries (Sarvanga Sundara) of Arunadatts and (Ayurveda rasayana) of Hemadri, edited by Bhishagacharya Harisastri paradakara Vaidya, 9th ed. Varanasi: Chaukamba Orientalia; 2005. 956pp.

Source of Support: Nil

Conflict Of Interest: None Declared

How to cite this URL: Mariswami & Ahalya S: A Study On Effect of Mustadi Shirolepa In Diabetic Retinopathy. International Ayurvedic Medical Journal {online} 2019 {cited September, 2019} Available from: http://www.iamj.in/posts/images/upload/1455_1462.pdf