



Research Article

EFFECT OF MRIDWEEKADI KASHAYA SEKA IN RETINAL HAEMORRHAGES ASSOCIATED WITH NON-PROLIFERATIVE DIABETIC RETINOPATHY – A CLINICAL STUDY

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ABSTRACT

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 this study, mild to moderate Non-proliferative diabetic retinopathy (NPDR) with retinal haemorrhages is considered as a *Timira* (symptomatically) and as *Abhishyanda* (considering etiopathogenesis) with *Kapha-pitta* predominance. *Mridweekadi kashaya*, predominantly *Kapha Pitta samana*, was selected for the study to be used as *Seka*.

Method: The study design was Interventional- pre and post evaluation without control, sample size fixed as 30 eyes. *Mridweekadi kashaya* was used as *Seka* for 21 days, twice daily. Fundus photographs were taken prior to commencement of *Seka*, on the 22nd day and then on 30th and 60th day after completion of the procedure. Change in extent of retinal hemorrhages were assessed as visualized in Fundus photographs and direct ophthalmoscopy. Change in visual acuity was assessed by LogMar Visual acuity chart and change in contrast sensitivity by Pelli-Robson contrast sensitivity chart consecutively, prior to the treatment, on the 10th day, 22nd day and then on 30th and 60th day after completion of procedure. Statistical analysis was done using Wilcoxon signed rank test and Paired t test according to the variable.

Result: Control in retinal haemorrhages associated with NPDR and improvement in visual acuity and contrast sensitivity.

Conclusion: *Mridweekadi kashaya seka* is effective in controlling retinal haemorrhages associated with NPDR.

KEYWORDS: NPDR, Retinal haemorrhages, *Mridweekadi kashaya*, *Seka*.

INTRODUCTION

Diabetes Mellitus can be defined as a metabolic cum vascular syndrome of multiple aetiologies characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both, leading to changes in both small blood vessels (microangiopathy) and large blood vessels (macroangiopathy), and which is often associated with long term damage, leading to malfunction and failure of various organs like eyes, kidneys, heart, nerves and blood vessels^[1].

Diabetic retinopathy (DR) is essentially a microangiopathy affecting arterioles, venules and capillaries of retina and is one among the dreadful complications of diabetes. It refers to the retinal changes seen in patients with diabetes mellitus. It is estimated that there will be a rapid increase in the

number of persons with diabetes mellitus world wide, particularly in the developing countries^[2].

With increase in the life expectancy of diabetics, the incidence of diabetic retinopathy has increased. Diabetic retinopathy, is a growing concern all over the world as it remains the leading cause of acquired vision loss in middle-aged and therefore economically active people. In Western countries, it is the leading cause of blindness^[3].

Affection of working age group takes a heavy toll in terms of loss of productivity, especially in a developing country like India. There is no cure to Diabetic retinopathy. No medical treatment has found to be beneficial in reversing or delaying DR.

The huge cost required for treatment, economic loss due to absenteeism from the work, etc.

has made it a public health challenge. Therefore it is the need of the hour to address the issue of diabetes with all its complications including DR with all seriousness and to search for affordable medical care for the same.

The classification used in the Early Treatment Diabetic Retinopathy Study (the modified Airlie House classification) is widely used internationally. The following descriptive categories are also in wide spread use in clinical practice^[4]:

1. Background diabetic retinopathy (BDR) is characterized by microaneurysms, dot and blot haemorrhages and exudates. Generally the earlier signs of DR, although persisting as more advanced lesions appear.
2. Diabetic maculopathy strictly refers to the presence of any retinopathy at the macula, but commonly reserved for significant changes, particularly vision threatening oedema and ischaemia.
3. Proliferative diabetic retinopathy (PPDR) manifests cotton wool spots, venous changes, intraretinal microvascular anomalies (IRMA) and often deep retinal haemorrhages. PPDR indicates progressive retinal ischaemia, with a heightened risk of progression to retinal neovascularization.
4. PDR is characterized by neovascularization on or within one disc diameter of the disc (NVD) and/or new vessels elsewhere (NVE) in the fundus.
5. Advanced diabetic eye disease is characterized by tractional retinal detachment, significant persistent vitreous haemorrhage and neovascular glaucoma.

In the early stages of Diabetic retinopathy, patients may be either asymptomatic or with mild visual symptoms. As the condition progresses, various visual symptoms are presented. While considering the symptoms, the non-proliferative stage of Diabetic retinopathy may be correlated to *Timira* with *Kapha-pitta* predominance mentioned in Susruta Samhita Uttaratantra, in the context of *Drishtigata netrarogas* and while analysing the etiopathogenesis in Ayurvedic perspective, there is an invariable *Netraabhishyanda* with *Kapha-pitta* predominance. Nature of *abhishyanda* is said to be *Aardreebhoota (Abhishyanne aardreebhoota)*^[5] which is similar to the *Kaphamedodravatwaprakruti* in *Prameha*. Acharya Vagbhata mentions *Abhishyanda* as a condition in which there is *Srotosyandana* in all channels of head and neck involving *Rakta dushti*^[6]. These may be correlated to the various vascular changes occurring in the retinal vessels in the pathogenesis of DR.

When *Pitta-rakta kara nidanas* are practised by a *Prameha rogi*, *Pitta-rakta kopa* occurs which causes *Dushti* of *Raktavahasrotas*. Like any other *srotas*, *Raktavahasrotodushti lakshanas*^[7] are *Atipravritti*, *Sanga*, *Siragranthi* and *Vimargagamana*. This can be seen in non-proliferative and proliferative stages of diabetic retinopathy.

Table 1: Table showing Raktavahasroto dushtilakshanas and their correlation

Raktavaha Srotodushti lakshanas	Correlation
<i>Atipravritti</i>	intra retinal microvascular abnormalities (IRMA) in NPDR and neovascularisation seen in PDR
<i>Sanga</i>	hypoxia and ischemia of retina
<i>Siragranthi</i>	micro aneurysms and intra retinal microvascular abnormalities seen in NPDR
<i>Vimargagamana</i>	Leakage from capillaries to retina and macular area through break down of blood retinal barrier, increase in vascular permeability and all haemorrhages (intra retinal, preretinal, subhyaloid and vitreous).

Raktadhatu kshaya and *Chirakaaritwa* of the disease lead to *Pranavayu kopa* which may cause *Indriyanasa*. This may be compared to the condition in advanced diabetic eye disease where retinal detachment due to pull on retina by fibro vascular bands from recurrent vitreous haemorrhages results in blindness.

It can be noticed that in successive stages of Diabetic Retinopathy, *Dosha* predominance varies from *Kapha* to *Pitta* and then to *Vata*, though there is involvement of all *Doshas* and *Rakta* in all stages.

Table 2: Table showing the predominant Dosha in the different stages of DR

Stage of Diabetic Retinopathy	Predominant Dosha
Back ground or early DR	<i>Kapha</i>
Pre Proliferative and Proliferative DR	<i>Pitta rakta</i>
Advanced Diabetic Retinopathy	<i>Vata</i>

All *Pramehas* are said to be *Tridoshaja*. Here, *Bahudrava sleshma*⁸ is the *Rogaarambhaka dosha*. In

the next stage of *Vyadhi*, involvement of *Pitta* and *Rakta* occurs. The *Avarana* or *Rodha* to *Raktadhatuvahana* created by *Sleshma*, *Cirakaritwa* of *Vyadhi* and *Dhatuksheenata* adds to *Vata kopa*. Here, in this study, NPDR with mild to moderate haemorrhages is considered as a *Timira* (symptomatically) and as *Abhishyanda* (considering etiopathogenesis) with *Kapha-pitta* predominance.

The study drug, *Mridweekadi kashaya*, is mentioned in *Sahasrayoga*^[9], a compilation of various Ayurvedic formulations, in the context of management of *Netrarogas*, for *Parisheka*. Most of the drugs in *Mridweekadi kashaya* is *Kapha-pitta samana*. In addition, many ingredient drugs have *Rakta-pitta samana* and *Raktaprasadana* property and are *Chakshushya*.

In the pathogenesis of *Timira*, there is involvement of *Patalas*^[10]. The diseases affecting *Patalas* are said to be severe and difficult to cure^[10]. *Seka* is a *Netrakriyakalpa* which can be used in *Balavattararogas*^[11]. It is mentioned in the *Samanya timira chikitsa*^[12], as a treatment modality.

Moreover, in the context of *Drishtigata netrarogas*, Acharya Susruta opines that suitable *Abhishyanda* treatment can be adopted in *Drishtigatarogas*^[13]. *Seka* is one among the primary treatment modalities mentioned in *Abhishyanda chikitsa*.

OBJECTIVE

To study the effect of *Mridweekadi kashaya seka* in retinal hemorrhages associated with Non-proliferative diabetic retinopathy.

METHODOLOGY

Study design

Interventional study pre and post evaluation without control.

Study setting

Department of Salakyatantra, Govt. Ayurveda College, Thiruvananthapuram.

Study population

Patients diagnosed as having Non-proliferative diabetic retinopathy, from OPD of Salakyatantra, Govt. Ayurveda College, Thiruvananthapuram, fulfilling the inclusion and exclusion criteria

Ethical Considerations

- Consent from the patients.
- Consent from Head of the Institute.
- Consent from Regional Institute of Ophthalmology – obtained prior to the study.

Inclusion Criteria

1. Patients aged 45-65 years irrespective of sex.
2. Mild and moderate NPDR patients with extent of retinal haemorrhages corresponding to Grade 1 and above as per the grading pattern.
3. Patients with well controlled blood sugar level.
4. Patients with well controlled Blood pressure and serum cholesterol level.
5. Patients having clear media on direct ophthalmoscopy.

Exclusion Criteria

1. Patients with severe and very severe NPDR, Proliferative diabetic retinopathy, Diabetic maculopathy, advanced diabetic eye disease.
2. Patients with other types of vascular retinopathies like Hypertensive retinopathy, Sick-cell retinopathy.
3. Patients with systemic disorders like renal and cardiac diseases.
4. Those who have already undergone photocoagulation.

Sample Size

30 eyes were studied.

Sampling Technique

Consecutive cases satisfying inclusion and exclusion criteria till attaining sample size.

Data Collection

Done by case proforma, laboratory investigations, clinical examination and investigations.

Study Tool

a. Case proforma

b. Investigations

- Ophthalmoscope
- Digital Retinal Camera
- LogMar Chart
- Pelli-Robson Contrast Sensitivity Chart

Examination of the patient

The patients were selected according to the inclusion criteria. The personal data, symptomatology and history of disease were taken in detail and noted in clinical case proforma. General examinations and eye examinations were done.

Study drug

The medicine selected for *Seka* in the study is *Mridweekadi kashaya*. It is not mentioned in any Ayurvedic classics. Its reference is from *Sahasrayoga*, a compilation of various Ayurvedic formulations, in the context of management of *Netrarogas*, for *Parisheka*. It is being used for *Seka* in the Department of Salakyatantra, Government Ayurveda College, Thiruvananthapuram for the past several years.

Ingredients

Mridweeka, Madhuka, Devadaru, Chandana, Musta, Sevyā, Aksha, Amalaki, Haritaki, Ikshu, Lodhra, Daruharidra and honey as *Prakshepadravaya*.

Table 3: Ingredient drugs of *Mridweekadi kashaya*

Ingredient Drugs	Botanical name	Family
<i>Mridweeka</i>	<i>Vitis vinifera</i> Linn.	Vitaceae
<i>Madhuka</i>	<i>Glycyrrhiza glabra</i> Linn.	Fabaceae
<i>Devadaru</i>	<i>Cedrus deodara</i> (Roxb.) Loud	Pinaceae
<i>Chandana</i>	<i>Santalum album</i> Linn.	Santalaceae
<i>Musta</i>	<i>Cyperus rotundus</i> Linn.	Cyperaceae
<i>Sevyā</i>	<i>Vetiveria zizanioides</i> (Linn.) Nash	Poaceae
<i>Aksha</i>	<i>Terminalia bellerica</i> (Gaertn.) Roxb.	Combretaceae
<i>Amalaki</i>	<i>Emblica officinalis</i> Gaertn.	Euphorbiaceae
<i>Hareetaki</i>	<i>Terminalia chebula</i> Retz.	Combretaceae
<i>Ikshu</i>	<i>Saccharum officinarum</i> Linn.	Poaceae
<i>Lodhra</i>	<i>Symplocos racemosa</i>	Symplocaceae
<i>Daruharidra</i>	<i>Berberis aristata</i> Dc.	Berberidaceae

Drug Analysis

The analytical study of *Mridweekadi kashaya* was conducted in the Drug Standardisation Unit under the Department of Rasashastra and Bhaishajyakalpana, Govt. Ayurveda College, Thiruvananthapuram.

Qualitative Analysis of *Mridweekadi Kashaya*

The presence of different plant constituents determines the pharmacological action and therapeutic potential of that plant. Testing for these phytoconstituents helps in determining the quality of the drug.

The methanolic extract of the study drug *Mridweekadi kashaya* was subjected to qualitative analysis for identification of various phytochemical constituents.

Table 4: Qualitative Analysis

Sl.No.	Phytochemicals	
1.	Alkaloids	++
2.	Steroids	++
3.	Phenolic compounds	++
4.	Flavanoid	++

Physicochemical Evaluation of *Mridweekadi Kashaya*

Specific gravity: 1.0196

Solid content: 5.61g/100ml

pH: 5.5

HPTLC Profile of *Mridweekadi kashaya*

HPTLC profiling of *Mridweekadi kashaya* was done with 2 extracts – Methanolic extract and Ethyl acetate extract in 2 tracks- Track1 and Track 2 respectively. The solvent system used was n-butanol: chloroform: acetic acid: ammonia: water in the proportion 7:7:5:2:1.

With Methanolic extract, 6 peaks were noted with Rf values 0.09, 0.31, 0.44, 0.60, 0.83 and 0.96. With Ethyl acetate extract, 6 peaks were noted with Rf values 0.11, 0.23, 0.39, 0.59, 0.83 and 0.92.

Clinical Study**Procedure**

The patients diagnosed as having NPDR with retinal hemorrhages on direct ophthalmoscopy and registered in OPD of Shalakyatantra, Govt. Ayurveda College Hospital, Thiruvananthapuram, were selected as per inclusion and exclusion criteria. After all clinical examination and investigations, grading was done and then *Mridweekadi kashaya seka* was done for the patients.

Intervention

Seka is done with *Mridweekadi kashaya* for 21 days twice daily (10.00 a.m, 3.00 p. m).

Patient is made to lie in supine position with eyes closed and the *Kashaya* is poured as *Sookshmadhara* from a height of 4 *Angula*^[14] (7.8cm)^[15] for a period of 600 *Matra*^[16,17].

Outcome Variable**Change in extent of retinal hemorrhages**

Fundus photographs were taken from the Regional Institute of Ophthalmology, Thiruvananthapuram, prior to the commencement of *seka*, on the 22nd day and then on 30th and 60th day after completion of the procedure. Change in extent of retinal hemorrhages were assessed as visualized in Fundus photographs and direct ophthalmoscopy.

Grading Pattern**Grading of retinal haemorrhages in Non-proliferative diabetic retinopathy**

Grade 0 - No intraretinal haemorrhage

Grade 1 - At least one intraretinal haemorrhage in 1 quadrant in the fundus photograph

Grade 2 - Intraretinal haemorrhages in 2 quadrants in the fundus photograph

Grade3 - Intraretinal haemorrhages in 3 quadrants in the fundus photograph

Change in Visual acuity

Assessed by LogMar Visual acuity chart by noting the change in visual acuity score value. Consecutive assessments of change in visual acuity were made prior to the treatment and on the 10th and 22nd day and then on 30th and 60th day after the completion of procedure.

Change in Contrast sensitivity

Assessed by Pelli-Robson Contrast sensitivity chart by noting the change in contrast sensitivity score value. Consecutive assessments of change in contrast sensitivity were made prior to the treatment and on the 10th and 22nd day and then on 30th and 60th day after the completion of procedure.

Statistical Analysis and Interpretation

Change in the Extent of Retinal Haemorrhage

Table 5: Distribution showing the extent of retinal haemorrhage at different stages of the treatment

Retinal Haemorrhage	BT		AT		F1		F2	
	N	%	N	%	N	%	N	%
Grade 0	0	0	3	10.0	10	33.3	18	60.0
Grade 1	7	23.3	11	36.7	13	43.3	9	30.0
Grade 2	13	43.3	12	40.0	7	23.3	3	10.0
Grade 3	10	33.3	4	13.3	0	0	0	0
Total	30	100.0	30	100.0	30	100.0	30	100.0

Graph No. 1: Graph showing the Percentage Grades of retinal haemorrhages in different stages

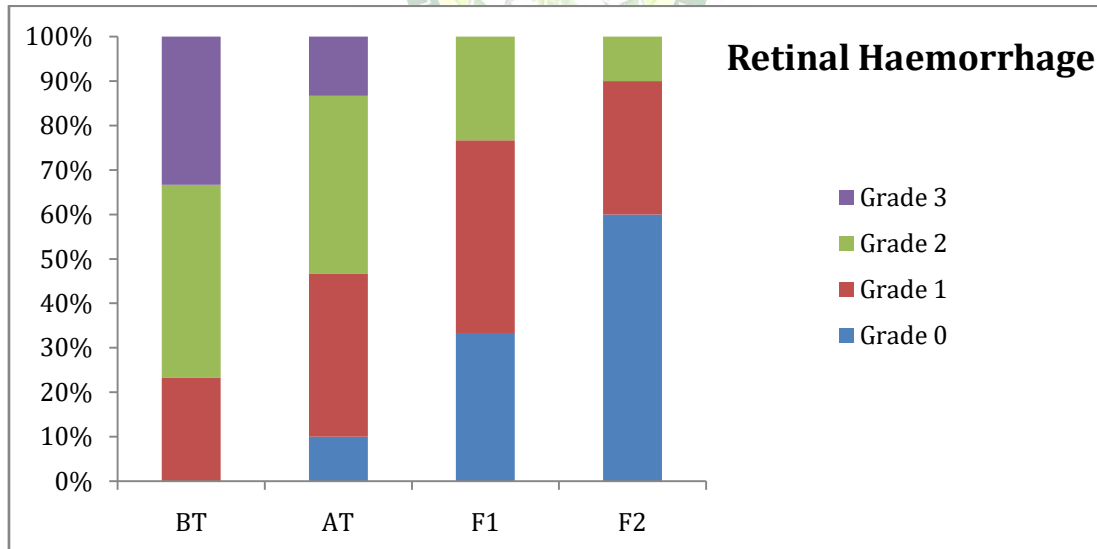


Table 6: Distribution showing the change in retinal haemorrhage at different stages of the treatment

Days of Assessment	Change in Retinal Haemorrhage							
	No Change		1 unit reduction		2 unit reduction		3 unit reduction	
	N	%	N	%	N	%	N	%
AT	14	46.67	16	53.33	0	0	0	0
F1	2	6.67	20	66.67	8	26.66	0	0
F2	0	0	14	46.67	14	46.67	2	6.66

Table 7: Statistical analysis of treatment response in retinal haemorrhage in the study group

Paired comparison	Wilcoxon signed rank test	
	Z	P
BT-AT	4.000	<0.001
BT-F1	4.850	<0.001
BT-F2	4.902	<0.001
AT-F1	4.472	<0.001
AT-F2	4.725	<0.001
F1-F2	3.464	.001

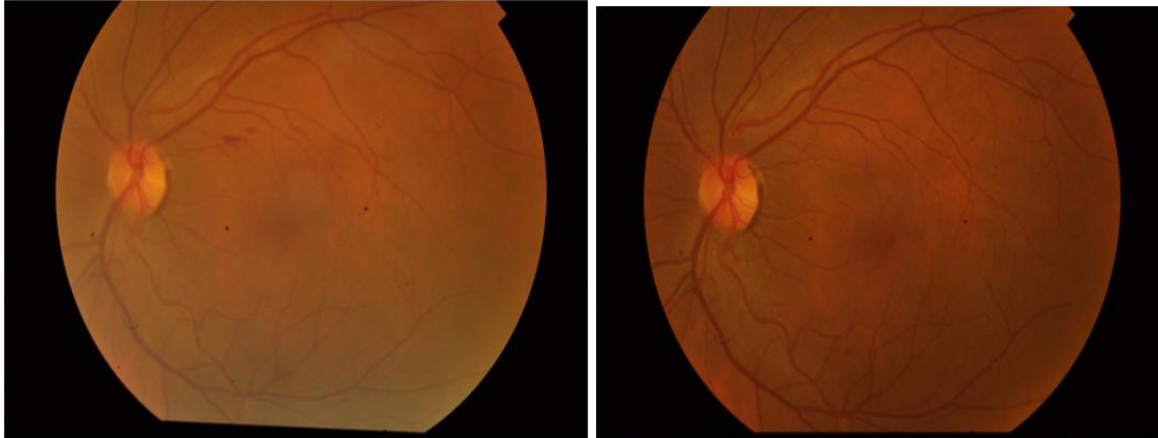


Figure 1: Fundus photographs of an NPDR case showing Grade 1 retinal haemorrhage involving Superotemporal quadrant before treatment and regression to Grade 0 after treatment

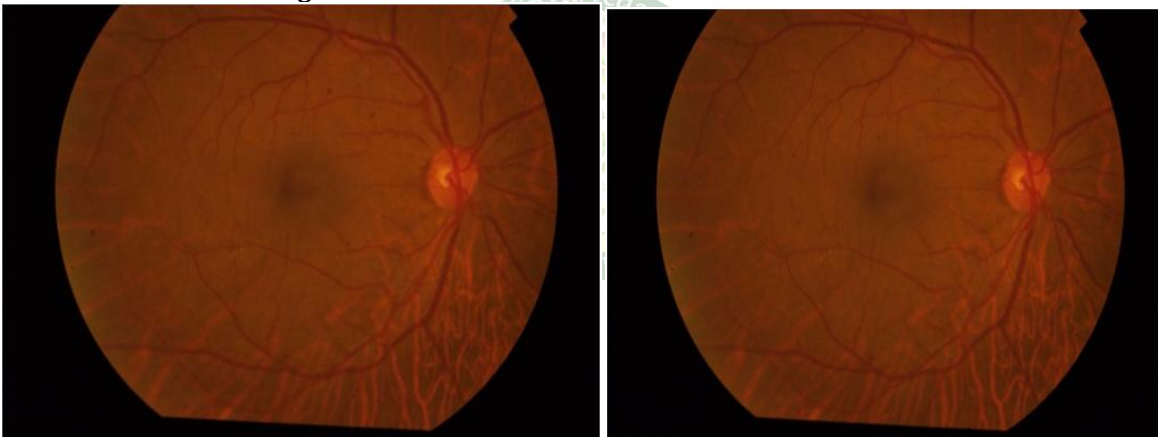


Figure 2: Fundus photographs of an NPDR case showing Grade 2 retinal haemorrhages involving Superotemporal and inferotemporal quadrants before treatment and regression to Grade 1 (inferotemporal) after treatment

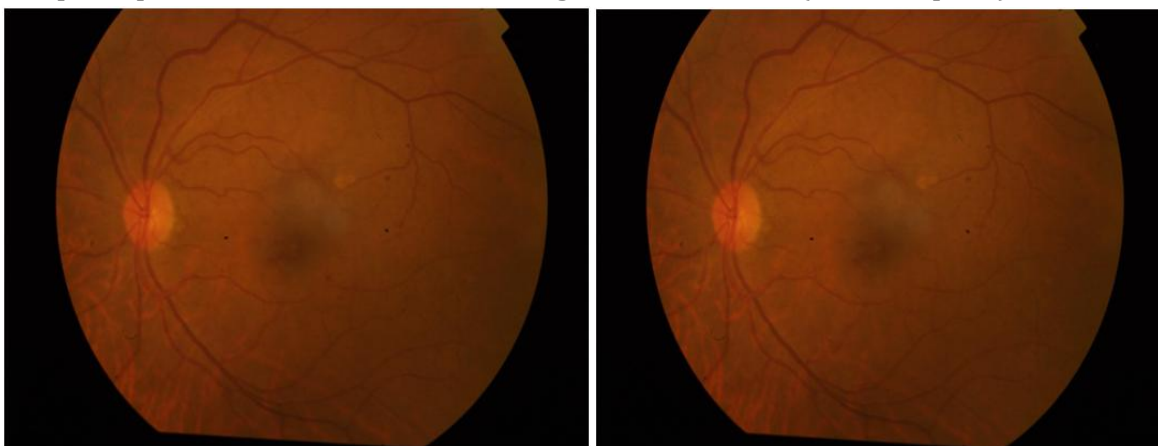


Figure 3: Fundus photographs of an NPDR case showing Grade 3 retinal haemorrhages involving Superotemporal, inferotemporal and inferonasal quadrants before treatment and regression to Grade 2 (superotemporal and inferonasal) after treatment

Change in Visual Acuity

Table 8: Table showing the mean Visual Acuity score of eyes in different stages of the treatment

Days of Assessment	No. of eyes	LogMAR Visual Acuity Assessment	
		Mean	SD
Before treatment (BT)	30	0.470	0.223
10 th day of treatment	30	0.360	0.206
After treatment (AT)	30	0.253	0.194
First follow up (F1)	30	0.237	0.196
Second follow up (F2)	30	0.230	0.200

Graph 2: Graph showing the mean Visual acuity score of eyes in different Stages

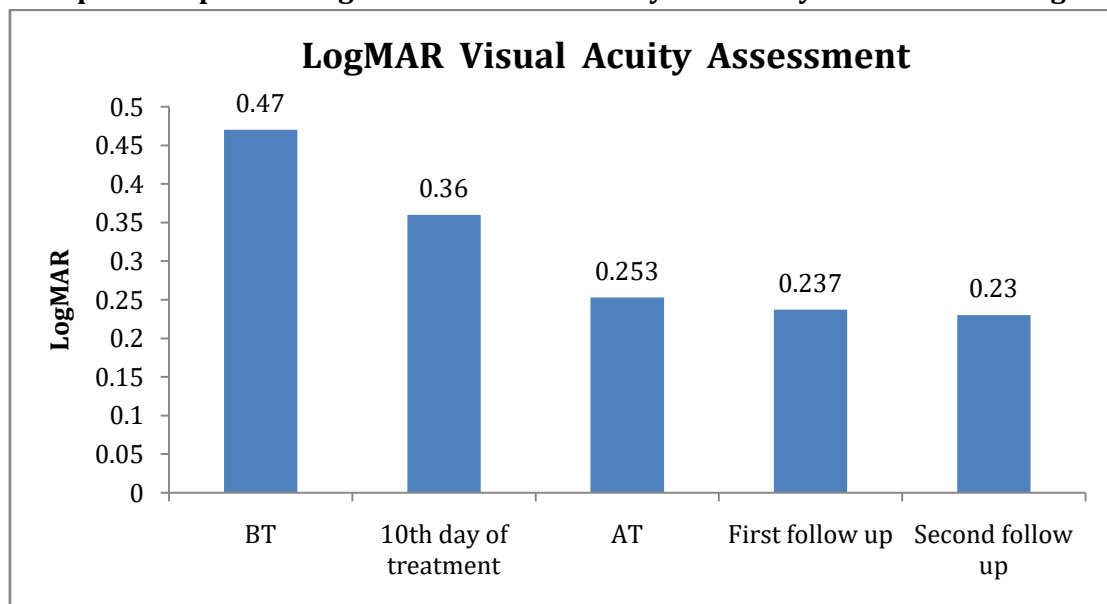


Table 9: Table showing paired comparison of Visual acuity score at different stages

Paired comparison	Paired Differences		Paired t test	
	Mean	SD	t	P
BT- 10th day	.110	.071	8.462	<0.001
BT- AT	.217	.083	14.231	<0.001
BT-F1	.233	.080	15.930	<0.001
BT- F2	.240	.089	14.697	<0.001
10th day - AT	.107	.064	9.133	<0.001
10th day - F1	.123	.068	9.950	<0.001
10th day - F2	.130	.070	10.140	<0.001
AT-F1	.017	.038	2.408	.023
AT-F2	.023	.043	2.971	.006
F1-F2	.007	.025	1.439	.161

Change in Contrast Sensitivity

Table 10: Table showing the mean Contrast Sensitivity score of eyes in different stages of the treatment

Days of Assessment	No: of eyes	Contrast Sensitivity Assessment	
		Mean	SD
Before treatment (BT)	30	2.09	0.09
10th day of treatment	30	2.15	0.08
After treatment (AT)	30	2.22	0.04
First follow up (F1)	30	2.24	0.02
Second follow up (F2)	30	2.24	0.02

Graph 3: Graph showing the mean Contrast Sensitivity score of eyes in different stages of the treatment

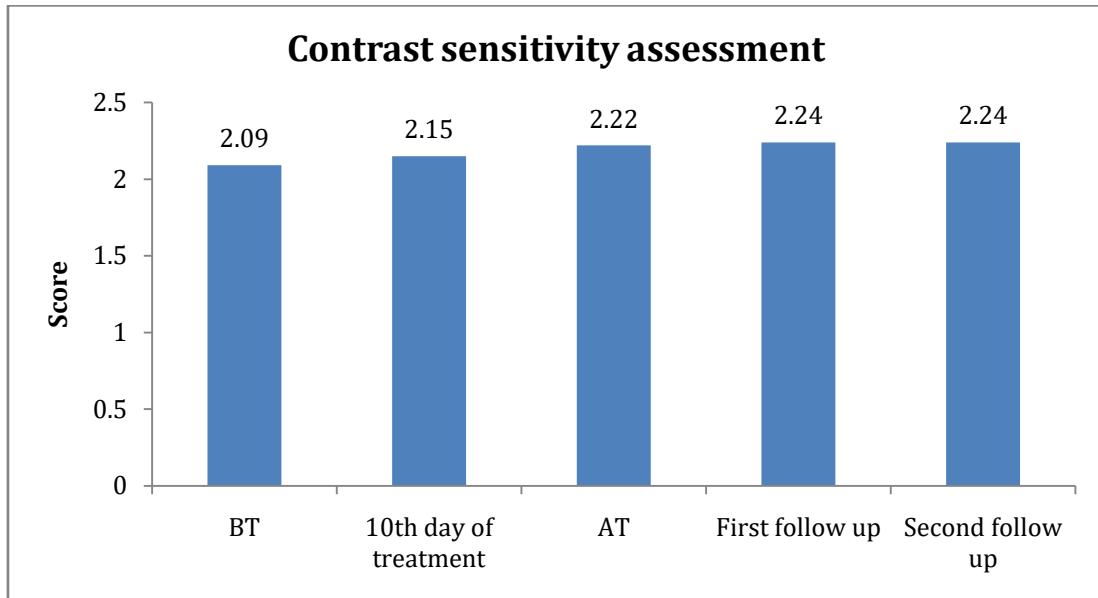


Table 11: Table showing paired comparison of Contrast Sensitivity score at different stages of the treatment

Paired comparison	Paired Differences		Paired t test	
	Mean	SD	t	P
BT- 10th day	.058	.054	5.887	<0.001
BT- AT	.128	.072	9.826	<0.001
BT-F1	.148	.085	9.607	<0.001
BT- F2	.152	.087	9.594	<0.001
10th day – AT	.070	.055	6.960	<0.001
10th day - F1	.090	.076	6.496	<0.001
10th day - F2	.093	.077	6.606	<0.001
AT-F1	.020	.034	3.247	.003
AT-F2	.023	.034	3.751	.001
F1-F2	.003	.013	1.439	.161

DISCUSSION

Discussion on Ayurvedic aspects of Non proliferative diabetic retinopathy

While considering the symptoms, the non-proliferative stage of Diabetic retinopathy may be correlated to *Timira* with *Kapha-pitta* predominance mentioned in *Susruta Samhita Uttaratantra*, in the context of *Drishtigatanetrarogas* and while analysing the etiopathogenesis in Ayurvedic perspective, there is an invariable *Netra abhishyanda* with *Kapha-pitta* predominance. Nature of *Abhishyanda* is said to be *Aardreebhoota (Abhishyanne aardreebhote)* which is similar to the *Kaphamedodravatwaprakruti* in *Prameha*.

Selection of Mridweekadi Kashayam for seka

Most of the drugs in *Mridweekadi kashaya* is *Kapha-pitta samana*. In addition, many ingredient drugs have *Rakta-pitta samana* and *Raktaprasadana* property and are *Chakshushya*. So the choice of medicine for *Seka* is apt.

Probable mode of action

Seka is beneficial due to the peculiarities in the procedure such as pouring the medicine from a particular height which provides a force that favours more penetration of the medicine, continuous flow of medicine in thin stream and increased surface area of contact of medicine which promotes its penetration.

Seka is given prime importance among the *Netrakriyakalpas* since it can be used in *Balavattara* condition. In Ayurveda, *Tiryag-Gata dhamanis*^[18] are mentioned which divide into innumerable branches, spreading throughout the body and open into hair follicles. All the topical applications like *Abhyanga*, *Parisheka*, *Avagaha* and *Alepa* applied over the skin surface undergoes *Pachana* by *Bhrajaka pitta* thereby releasing their *Virya*. This *Virya* or active principle of the drug reaches the intended target tissue through these net work of *Tiryag-gatadhamanis*.

CONCLUSION

In this study, NPDR with mild to moderate haemorrhages is considered as a *Timira* (symptomatically) and as *Abhishyanda* (considering etiopathogenesis) with *Kapha-pitta* predominance. *Mridweekadi kashaya seka* is effective in controlling intra retinal haemorrhages in mild to moderate NPDR. The intervention is effective as the study group showed significant reduction in the extent of haemorrhage on the assessment made after the treatment and during the follow up. No recurrence of intra retinal haemorrhages was noticed in the study group during and after the treatment and during the two follow up assessments made on 30th day and 60th day after completing the treatment. *Mridweekadi kashayaseka* is effective in improving the contrast

sensitivity and visual acuity as the study group showed statistically significant change in the contrast sensitivity and visual acuity score during and after treatment and the result was improved or sustained in the two follow up assessments. *Mridweekadi kashaya seka* is cost effective, affordable and is a convenient form of ocular therapy. Long duration studies are to be conducted with longer follow-up period to assess the persistent effect. Evaluation of biochemical changes on administration of *seka* with the medicine has to be done incorporating advanced technologies.

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