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. Preproliferative 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 Kaptha-pitta predominance mentioned in
Susruta Samhita Uttaratantra, in the context of
Drishhtgata netrarogas and while analysing the
etiopathogenesis in Ayurvedic perspective, there is an
invariable Netraabhishyanda with Kaptha-pitta
predominance. Nature of abhisshyanda is said to be
Aardreebhoota (Abhishyane aardreebhoote)[5]
which is similar to the Kaphamedodratwaprakruti in
Prameha. Acharya Vagbhata mentions Abhisshyanda
as a condition in which there is Srotosyandana in all
channels of head and neck involving Rakta dushhti[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 |
|---------------------------------|-------------|
| Atipravritti                    | intra retinal microvascular abnormalities (IRMA) in NPDR and neovascularisation seen in PDR |
| Sanga                           | hypoxia and ischemia of retina |
| Siragranthi                     | micro aneurysms and intra retinal microvascular abnormalities seen in NPDR |
| Vimargagamana                   | 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 Kaptha 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                    | Kaptha           |
| Pre Proliferative and Proliferative DR      | Pitta rakta      |
| Advanced Diabetic Retinopathy              | Vata             |

All Pramehas are said to be Tridoshaja. Here,
Bahudrava sleshma[8] is the Ragaarambhaka dosha. In
the next stage of Vyadhi, involvement of Pitta and Rakta occurs. The Avarana or Rodha to Rakadhatuvahana created by Sleshma, Cirakaritwa of Vyadhi and Dhatuksheenata 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, 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. The diseases affecting Patalas are said to be severe and difficult to cure. Seka is a Netrakriyakalpa which can be used in Balavattararogas. It is mentioned in the Samanya timira chikitsa, as a treatment modality.

Moreover, in the context of Drishtigata netrarogas, Acharya Susruta opines that suitable Abhishyanda treatment can be adopted in Drishtigatarogas. 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 Salakyantra, Govt. Ayurveda College, Thiruvananthapuram.

**Study population**

Patients diagnosed as having Non-proliferative diabetic retinopathy, from OPD of Salakyantra, 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, Sickle-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 Salakyantra, Government Ayurveda College, Thiruvananthapuram for the past several years.
Ingredients

Mridweeka, Madhuka, Devadaru, Chandana, Musta, Sevya, Aksha, Amalaki, Haritaki, Ikshu, Lodhra, Daruharidra and honey as Prakshepadravya.

Table 3: Ingredient drugs of Mridweekadi kashaya

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

Drug Analysis

The analytical study of Mridweekadi kashaya was conducted in the Drug Standardisation Unit under the Department of Rasasastra 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 – Atleast one intraretinal haemorrhage in 1 quadrant in the fundus photograph
Grade 2 - Intraretinal haemorrhages in 2 quadrants in the fundus photograph
Grade 3 - 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    | %    |
| Grade 0             | 0   | 0   | 3    | 10.0 |
| Grade 1             | 7   | 23.3| 11   | 36.7 |
| Grade 2             | 13  | 43.3| 12   | 40.0 |
| Grade 3             | 10  | 33.3| 4    | 13.3 |
| Total               | 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                | %                |
| AT                 | 14                             | 46.67     | 16               | 53.33            | 0                |
| F1                 | 2                              | 6.67      | 20               | 66.67            | 8                | 26.66            | 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 |
|--------------------|-------------|---------------------------------|
| Before treatment (BT) | 30          | Mean 0.470, SD 0.223            |
| 10th day of treatment | 30          | Mean 0.360, SD 0.206            |
| After treatment (AT)  | 30          | Mean 0.253, SD 0.194            |
| First follow up (F1)  | 30          | Mean 0.237, SD 0.196            |
| Second follow up (F2) | 30          | Mean 0.230, SD 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 Nethra abhishyanda with Kapha-pitta predominance. Nature of Abhishtyanda is said to be Aardreebhoota (Abhishyanne aardreebhoote) which is similar to the Kaphamedodravatwapakruti 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 Raktabrasodana 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, Tirayag-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 Tirayag-gatadhimanis.

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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