A COMPARATIVE STUDY ON TAKRADHARA AND VAASAKAADI KWATHA ORALLY IN THE MANAGEMENT OF DIABETIC RETINOPATHY

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ABSTRACT

Introduction: Diabetic Retinopathy is a highly specific vascular complication of both IDDM and NIDDM. It is one of the commonest causes of moderate to severe retinal blindness. Need for the Study: An estimated 31.7 million population have Diabetic Mellitus as per WHO. Approximately 8% of legally blind individuals with Diabetic Mellitus & 12% of new blindness are due to Diabetic Retinopathy in India. In Type I, the prevalence of Diabetic Retinopathy is 97.5%, if the duration is 15 years or more, & in Type II, it is almost 80%. Objectives: The objective of study is to evaluate the efficacy of Takradhara and Vaasakaadi Kwathapana in the management of Diabetic Retinopathy and to evaluate the efficacy of tuvarakadi Anjana as an established study. Study Design: Selected 45 patients were randomly divided into three groups as Group 'A', Group 'B' & Group 'C' with 15 patients in each. Group 'A' & 'B' were trial groups, Group 'C' was taken as an established study. Observation and conclusion: The process of Takradhara might accelerate the function of tarpaka kapha, and may also bring in the specific action as demanded by the disease condition like blockage of channels by kapha which can be taken as micro vascular occlusion which is the basic pathological process seen in Diabetic Retinopathy. It also helps in the proper nourishment of retina, thereby preventing further vascular leakage and the chakshusya property of drugs helps in the improvement of vision. Vaasakaadi kwatha does Prameha samprapthi bhanga, also augments the absorption of intra retinal haemorrhages and exudates. The drugs with their antioxidant property prevents from oxidative stress damage to the endothelium of retinal vasculature, by helping in proper nourishment of retina prevents further leakage. Although various treatments are available for Diabetic Retinopathy like Photocoagulation, Vitrectomy, but can only retain the existing vision rather than regain vision as it leads to permanent tissue atrophy, denatures cellular elements. Owing to the problems and adverse effects of different medicaments and surgeries employed to manage DR, it is imperative to explore a potent ayurvedic drug schedule which could tackle effectively this problem at biological level without adverse effects; hence this study was taken up. Result: The overall success rate of improvement by the treatments in the individual groups is 17.25%, 27.84% & 14.24% in Group A, B & C respectively. Overall assessment of the results of DR showed that its regression success rate being highest in patients of Group B treated with Vaasakaadi kwatha pana (60%), followed by in Group A Takradhara (55%) and Group C Tuvarakadi Anjana (26%).

Keywords: DR- Diabetic retinopathy, Prameha- Diabetes, Vitrectomy- Retinal surgery,
I & Type II Diabetic Mellitus. It is one of the commonest causes of moderate to severe retinal blindness.

WHO has labelled India as “the diabetic capital of the world” as it has the highest number of diabetic patients. An estimated 31.7 million population have Diabetic Mellitus as per WHO, 2 million in Bangalore itself. The estimated 57 million persons with diabetes in India by 2025 have implications for the National Programme for Control of Blindness in India. 10% of Diabetic populations have Type I diagnosed within 40 years of age. Majority of Diabetic patients have Type II diagnosed later than 40 years of age. In Type I, the prevalence of Diabetic Retinopathy is 97.5%, if the duration is 15 years or more, & in Type II, it is almost 80%. After 20 years of Diabetic Mellitus, nearly all patients with Type I & more than 60% of patients with Type II have some degree of Diabetic Retinopathy. There are many challenging problems especially of problems retained with management of conditions existing before modern ophthalmologists and DR is one among them. LASER is the latest advancement and which is widely used in treatment of DR compared to medical management with Anti VEGF’s and Vitreectomy surgery. All these treatments have their own limitations and complications. This can only retain the existing vision rather than regain vision which has been lost. Ayurveda has long history of treating Diabetes; hence intervening Ayurvedic treatment in earlier stages may give promising results in the management of diabetic Retinopathy.

OBJECTIVES OF THE STUDY
1. To evaluate the efficacy of Takradhara in the management of Diabetic Retinopathy.
2. To evaluate the efficacy of Vaasakaadi Kwathapana in the management of Diabetic Retinopathy.
3. To evaluate the efficacy of Tuvarakadi Anjana in the management of Diabetic Retinopathy.
4. To evaluate the comparative superiorities of Takradhara and Vaasakaadi Kwathapana in the management of Diabetic Retinopathy with Tuvarakadi Anjana as the established study.

MATERIALS AND METHODS
Source of Data
This was a hospital based clinical study of 45 patients of known cases of Diabetes diagnosed by investigations, who were selected from the OPD, IPD and those referred to Nethra vibhaga of Post Graduate Department of Shalakyatantra for screening and evaluation at G.A.M.C and Sri Jayachamarajendra Institute Of Indian Medicine Hospital Bangalore

The patients were selected irrespective of age and sex. They were not withdrawn from regular Antidiabetic tablets. The yogas selected in the present study are “Takradhara” mentioned in Sahasrayoga, Uttararda, Dharakalpa. “Vaasakaadi Kwatha mentioned in Vangasena Samhita, Netraroga Adikara and Tuvarakaadianjana” mentioned in Sushruta Samhita, Madhumehachikitsa adhyaya.

INCLUSION CRITERIA:
1. Patients of DM (Type 1&Type 2) between the ages 30-70 years having opthalmoscopically detectable DR
changes.
2. Patient with history of 5 to 10 years or more duration of Type 1 and Type 2 Diabetic Mellitus, attending OPD and IPD of SJIIM Hospital, Bangalore were taken for the study.
3. Patient with symptom like blurred vision was included.
4. Patient of Non proliferative diabetic retinopathy was included.
5. Patients with good glycaemic control were taken for the study.

**EXCLUSION CRITERIA:**
1. Patient with Diabetic maculopathy, proliferative diabetic retinopathy, high risk proliferative diabetic retinopathy, advanced diabetic eye disease, other types of vascular retinopathies like hypertensive retinopathy, retinopathies of blood dyscrasias, gestational diabetic retinopathy, retinopathy of prematurity, sickle cell retinopathy were excluded.
2. Patients of DR who have media opacities due to well-developed cataract or any other causes which is sufficient to interfere with detailed examination of fundus.
3. Patient with other systemic disorders like renal diseases, chronic hyperglycaemia, hyperlipidemia, cardiovascular diseases were excluded.
4. Patients of DR who have undergone Laser Photocoagulation therapy previously for the same but with persisting symptoms and/or signs were excluded.
5. Patients with Aided Visual Acuity less than 6/60 at Snellen’s distant chart.
6. Extremely debilitated patients were excluded from the study.

**STUDY DESIGN**

**Nature of Study**
Selected 45 patients were randomly divided into three groups as Group ‘A’, Group ‘B’ & Group ‘C’ with 15 patients in each. Group ‘A’ & ‘B’ were trial groups, Group ‘C’ was taken as an established study.

**Study Design of Group A, B & C**

<table>
<thead>
<tr>
<th>Group</th>
<th>Chikitsa</th>
<th>Prayogakaala</th>
<th>Prayogaavadhi</th>
<th>Nireekshanaavadhi</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Takradhara</td>
<td>Morning</td>
<td>5 days with a gap of 1 week for 48 days, both inclusive (4 sittings)</td>
<td>3 months</td>
</tr>
<tr>
<td>B</td>
<td>Vaasakaadi Kwatha</td>
<td>Morning (orally)</td>
<td>48 days continuously</td>
<td>3 months</td>
</tr>
<tr>
<td>C</td>
<td>Tuvarakadi Anjana</td>
<td>Morning (application)</td>
<td>5 days with a gap of 1 week for 48 days, both inclusive</td>
<td>3 months</td>
</tr>
</tbody>
</table>

**Follow up:** Follow up period was fixed to 90 days (3 months). During this period the patients were asked to visit once in every 15 days for any recurrence or otherwise. The patients in all three groups were advised to control their blood sugar level if present.

**Preparation of the Drugs**

**Group A- Preparation of Takradhara:**
Amalaki which are dried for 1 year in sun & shade, which are devoid of seeds, are taken in the quantity of one and quarter prastha (80 karsha=960 gms). To this add 18 kuduva
(288 karsha=3456gms) water and reduce it to 1/6th (750gms) part by boiling. Again to this equal part of amlataka is added. This preparation is used for shirodhara as per the procedure told by the ancient acharya’s.

**Group B- Preparation of Vaasakaadi kwatha:**
The Vaasakaadi kwatha contains ingredients like Vasa, Nimba, Musta, Haritaki, Bibhitaki & Amalaki which were taken in equal quantity and powdered separately. The kwatha was prepared according to Acharya Sharangadhara’s view of method of preparation of Madhyama Kashaya Kalpana Vidhi. To prepare Madhyama kashaya, 8 parts of water added to the 1 part of coarse powder and reduced to 1/4th part after boiling. The dose of the general kwatha is 1 Pala (48ml).

**Group C- Preparation of Tuvarakadi Anjana:**
It contains ingredients like Tuvaraka taila, Saindhava lavana & Anjana. **Procedure:** The eye of the patient is opened with left hand. Then holding the shalaka dipped in anjana with right hand anjana is smeared from kaneenika to apanga sandhi on the inner side of the eyelid uniformly. The same procedure is repeated to the other eye also. It was applied once daily in the morning for 5 days with a gap of one week for 48 days.

When tears start flowing out of the eye, it is washed with lukewarm water.

The eight parameters included for assessment are-

**Subjective Parameter:**
- Blurred vision

**Objective Parameter:**
1. Micro aneurysms
2. Intra retinal haemorrhages(Superficial flame shaped and deep dot-blots)
3. Exudates (Soft Exudates and Hard Exudates)
4. Intra retinal microvascular abnormalities
5. Venous beading, Looping, Dilatation
6. Best corrected visual acuity
7. Colour Fundus Photography

**Criteria for overall assessment of effect of Treatment (Assessment of Response)**
Regression - Means coming to previous stage of DR- 0
Maintained- Maintaining the existing stage of DR-1
Progressed - Progression of the disease to next stage-2

**OBSERVATIONS AND RESULTS**

**RESULTS**

**SHOWING INDIVIDUAL STUDY OF THE PARAMETERS IN GROUP A**
Comparative study of the parameters in Group B

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Average</th>
<th>Differ</th>
<th>% of differ</th>
<th>SD</th>
<th>SE</th>
<th>df</th>
<th>T value</th>
<th>P value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>BT</td>
<td>1.2667</td>
<td>0.6667</td>
<td>0.6</td>
<td>47.393</td>
<td>0.4807</td>
<td>29</td>
<td>6.837</td>
<td>&lt;0.0001</td>
<td>HS</td>
</tr>
<tr>
<td>AT</td>
<td>0.611</td>
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</tr>
<tr>
<td>MA</td>
<td>1.233</td>
<td>0.633</td>
<td>0.633</td>
<td>51.338</td>
<td>0.4901</td>
<td>29</td>
<td>7.077</td>
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<td>HS</td>
</tr>
<tr>
<td>IRH</td>
<td>1.23</td>
<td>0.58</td>
<td>0.58</td>
<td>47.154</td>
<td>0.4928</td>
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<td>Exudates</td>
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<td>0.633</td>
<td>0.67</td>
<td>9.571</td>
<td>0.1729</td>
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<td>2.112</td>
<td>&lt;0.05</td>
<td>S</td>
</tr>
<tr>
<td>IRMA</td>
<td>0.20</td>
<td>0.20</td>
<td>0.20</td>
<td>0</td>
<td>0</td>
<td>29</td>
<td>0</td>
<td>&gt;0.05</td>
<td>NS</td>
</tr>
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<td>Venous abnormalities</td>
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<td>0.133</td>
<td>0.133</td>
<td>0</td>
<td>0</td>
<td>29</td>
<td>0</td>
<td>&gt;0.05</td>
<td>NS</td>
</tr>
<tr>
<td>BCVA</td>
<td>0.7167</td>
<td>0.83</td>
<td>0.1133</td>
<td>15.813</td>
<td>0.08996</td>
<td>29</td>
<td>6.901</td>
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<td>HS</td>
</tr>
<tr>
<td>CFP</td>
<td>1.2667</td>
<td>0.7666</td>
<td>0.5</td>
<td>39.476</td>
<td>0.5085</td>
<td>29</td>
<td>5.385</td>
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</table>

Showing Individual study of the Parameters in Group C

<table>
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<th>Parameter</th>
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<th>% of differ</th>
<th>SD</th>
<th>SE</th>
<th>df</th>
<th>T value</th>
<th>P value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>BT</td>
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<td>0.9167</td>
<td>0.58333</td>
<td>38.889</td>
<td>0.4170</td>
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<tr>
<td>AT</td>
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<tr>
<td>MA</td>
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<td>0.38333</td>
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<td>IRH</td>
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<td>0.13333</td>
<td>9.524</td>
<td>0.3198</td>
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<td>&lt;0.01</td>
<td>HS</td>
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<td>Exudates</td>
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<td>0.03333</td>
<td>3.333</td>
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<td>29</td>
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<td>NS</td>
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<tr>
<td>IRMA</td>
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<td>0.2</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Venous abnormalities</td>
<td>0.33333</td>
<td>0.3</td>
<td>0.03333</td>
<td>9.999</td>
<td>0.1269</td>
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<td>1.439</td>
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<tr>
<td>BCVA</td>
<td>0.66333</td>
<td>0.7567</td>
<td>0.09334</td>
<td>14.071</td>
<td>0.09444</td>
<td>29</td>
<td>5.413</td>
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<td>HS</td>
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<tr>
<td>CFP</td>
<td>1.4</td>
<td>1.3</td>
<td>0.1</td>
<td>7.143</td>
<td>0.3051</td>
<td>29</td>
<td>1.795</td>
<td>&lt;0.10</td>
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Comparative study of the Rx effect on BCVA in Group AC-BC-AB

<table>
<thead>
<tr>
<th>Group</th>
<th>Average</th>
<th>% Success Rate</th>
<th>SE</th>
<th>t-value</th>
<th>P Value</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>AC</td>
<td>Group A</td>
<td>0.06207</td>
<td>9.231</td>
<td>1.680</td>
<td>&lt;0.10</td>
<td>HS</td>
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<tr>
<td></td>
<td>Group C</td>
<td>0.09334</td>
<td>14.071</td>
<td>0.08666</td>
<td>0.02257</td>
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<tr>
<td>BC</td>
<td>Group B</td>
<td>0.11333</td>
<td>15.813</td>
<td>0.09601</td>
<td>0.02479</td>
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<tr>
<td></td>
<td>Group C</td>
<td>0.09334</td>
<td>14.071</td>
<td>0.02257</td>
<td>0.02479</td>
<td>0.5378</td>
</tr>
<tr>
<td>AB</td>
<td>Group A</td>
<td>0.06207</td>
<td>9.231</td>
<td>0.09444</td>
<td>0.02479</td>
<td>0.5378</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>0.11333</td>
<td>15.813</td>
<td>0.09444</td>
<td>0.02479</td>
<td>0.5378</td>
</tr>
</tbody>
</table>

Comparison of Overall Affect of Treatments (Except BCVA) between the Groups A, B & C.

<table>
<thead>
<tr>
<th>Group</th>
<th>Average Mean</th>
<th>% of Success Rate</th>
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<tbody>
<tr>
<td>A</td>
<td>0.1725</td>
<td>17.25%</td>
</tr>
<tr>
<td>B</td>
<td>0.2784</td>
<td>27.84%</td>
</tr>
<tr>
<td>C</td>
<td>0.1424</td>
<td>14.24%</td>
</tr>
</tbody>
</table>

During 90 days of follow up period, among 89 eyes of 45 patients, 34.483% in Group A, 6.667% in Group B and 35.955% in Group C had recurrence of features.

Showing Overall Assessment of results in Group A, B & C

<table>
<thead>
<tr>
<th>DR</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No of Eyes</td>
<td>%</td>
<td>No of Eyes</td>
<td>%</td>
</tr>
<tr>
<td>Regressed</td>
<td>16</td>
<td>55.17</td>
<td>18</td>
<td>60</td>
</tr>
<tr>
<td>Maintained</td>
<td>09</td>
<td>31.03</td>
<td>10</td>
<td>33.33</td>
</tr>
<tr>
<td>progressed</td>
<td>04</td>
<td>13.79</td>
<td>02</td>
<td>6.67</td>
</tr>
<tr>
<td>Total Eyes</td>
<td>29</td>
<td>30</td>
<td>30</td>
<td>89</td>
</tr>
</tbody>
</table>

Among 89 Eyes of 45 patients of DR, taken for the study, 42 Eyes (47.19%) were
Regressed from previous status, 31 Eyes (34.83%) maintained their earlier status, whereas 16 Eyes (17.98%) were Progressed from their earlier status.

**DISCUSSION ON PROCEDURES**

DR is predominantly a microangiopathy in which small bloodvessels are particularly vulnerable to damage from hyperglycaemia. Main pathological process involved is microvascular occlusion and leakage.

**Mode of action:**
Takradhara action can be understood in 2 ways- Pharmacologic action of substances absorbed through the skin (Therapeutical effect), The Procedural effect of Takradhara induced by the somato-autonomic reflex through thermosensors or pressure sensors in the skin or hair follicles via the trigeminal cranial nerve. The process of Takradhara might accelerate the function of tarpaka kapha, and may also bring in the specific action as demanded by the disease condition like blockage of channels by kapha which can be taken as micro vascular occlusion which is the basic pathological process seen in Diabetic Retinopathy. Apart from this, It also helps in the proper nourishment of retina, thereby preventing further vascular leakage and the chakshusya property of drugs helps in the improvement of vision.Further, Takradhara decreases the sympathetic nervous stimulation there by reducing the rate of metabolic activities and glucose release into the blood and regulates Diabetes and probably reverse the pathology of DR. Vaasakaadi kwatha does Prameha samprapthi bhanga, also augments the absorption of intra retinal haemorrhages and exudates. The drugs with their antioxidant property prevents from oxidative stress damage to the endothelium of retinal vasculature, by helping in proper nourishment of retina prevents further leakage.

**CONCLUSION**
The following conclusion is drawn after considering the clinical aspects and theoretical facts. After observing the results of the t-values of Group A, Group B & Group C in detail we can come to the conclusion that, the patients of Group B responded well, when compared to the subjects of Group A and Group C. All the three groups showed statistical significance. After comparing the overall improvement in treatments between the groups AC, BC & AB, it was observed that the difference in the treatments between the groups is not statistically significant. However the overall success rate of improvement by the treatments in the individual groups is 17.25%, 27.84% & 14.24% in Group A, B & C respectively. Overall assessment of the results of DR showed that its regression success rate being highest in patients of Group B treated with Vaasakaadi kwatha pana (60%), followed by in Group A Takradhara (55%) and Group C Tuvarakadi Anjana (26%). The disease DR was well maintained in all 3 groups. The highest Progression rate of DR (33%) is seen in Group C (Tuvarakadi Anjana) followed by in Group A (13%) with Takradhara and Group B (6.6%) with Vaasakaadi kwathapana. This shows that the oral treatment (Vaasakaadi kwatha) is better in the management of DR compared to other treatments like Takradhara and Tuvarakadi.
Anjana, as DR is an ocular manifestation of systemic disease.

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