Efficacy of Yashad Bhasma with Triphala Churna in Prameha (Type 2 Diabetes Mellitus) with Special Reference to BSL and HbA1C

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ABSTRACT

Prevalence of type - II diabetes is increasing in all countries, especially in India, at an alarming rate. Various factors contribute to the rise in prevalence of type -II diabetes that include body fat distribution, rapid changes in eating habits, and lifestyles that are increasingly sedentary. In this trial total 10 Subjects who was showing high BSL Fasting>130mg/dl, pp>180mg/dl and HbA1c >6.5mol. were selected from Kayachikitsa OPD of D. Y. Patil Ayurvedic Hospital, Nerul, Navi Mumbai. Yashad Bhasma (zinc ash) 100 mg +Triphala Churna 2 gms BD before Lunch and Dinner was given with warm water for three months. Data was recorded in CRF during regular monthly intervals. Statistical analysis done with help of paired t test and Wilcoxon matched-pairs signed-rank test. The study showed reduction of FBS, PPBS, and HbA1C values before and after the trial at the level of significance p<0.01. The study also showed reduction of subjective parameters at level of significance p<0.01.

Keywords: type - II Diabetes Mellitus, Prameha, Triphala Churna, Yashad Bhasma

INTRODUCTION

- Drastically modified lifestyle, lack of physical activity, improper unbalanced diet and stress are known causative factors for prameha (DM). Prameha (Diabetes Mellitus) is a metabolic diseases in which there is a high BSL & symptoms like Avilmootrata, Prabhutmutrata, Naktamootrata, ati pipasa, Hastapadtalada
- India is among top countries with high Diabetic population & it is predicted to be increased in next decade. Modern oral Hypoglycaemic drugs are having many side effects (1)(5)(6), so there is need of Ayurvedic medicine which can be taken on regular bases to achieve normal blood sugar levels. So this clinical study Efficacy OF Yashad bhasma with Triphala churna in Prameha (TYPE 2 DIABETES MELLITUS) was undertaken in D.Y. Patil University School of Ayurveda
- Yashad (Jasad) Bhasma contains calcined and pure zinc. It is highly absorbable zinc supplement because of the decreased particle size and nanotechnology. Pramehahar (antidiabetic) formulations having Triphala as the main ingredient are very well defined in Brihatrayee especially in the chapters dealing with the treatment of Prameha so I used mixture of Yashad bhasma and Triphala to get additive effect in Diabetes management.

AIM OF THE STUDY: Assessment of changes in BSL before and after the study.

OBJECTIVES:

PRIMARY OBJECTIVE:
- Assessment of changes in HbA1c % (Glycosylated Hemoglobin %) levels

SECONDARY OBJECTIVE:
• To assess clinical symptoms of Diabetes like Polyuria (Prabhutmutrata), polydipsia (Atipipasa), Polyphagia, Fatigue in type II Diabetes subjects.

MATERIALS AND METHODS

Triphala (3)(8) is an important Ayurvedic herbal formulation consisting of the dried fruits of three medicinal plants Terminalia chebula, Terminalia bellerica, and Emblica officinalis. Triphala means “three” (tri) “fruits” (Phala) and are popularly known in India as Harada, Baheda, and Amla, respectively. The formulation is prescribed as the first line of treatment in Diabetes Mellitus.

Table 1. Yashad (Jasad) Bhasma(4)(5) contains calcined and pure zinc. Mixture of Triphala Churna and Yashad Bhasma are used in this study.

<table>
<thead>
<tr>
<th>Sr.No.</th>
<th>Name of the drug</th>
<th>Latin Name</th>
<th>Rasa</th>
<th>Guna</th>
<th>Virya</th>
<th>Vipaka</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amalaki</td>
<td>Emblica officinalis, Pancharasa except Lavanrasa</td>
<td>Guru, Ruksha, Sheeta</td>
<td>Shia</td>
<td>Madhur</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Haritaki</td>
<td>Terminalia chebula, Pancharasa except Lavanrasa</td>
<td>Laghu, Ruksha</td>
<td>Shia</td>
<td>Madhur</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Bibhitaki</td>
<td>Terminalia Bellirica</td>
<td>Kashaya</td>
<td>Laghu, Ruksha</td>
<td>Ushna</td>
<td>Madhur</td>
</tr>
<tr>
<td>4</td>
<td>Yashad Bhasma</td>
<td>Zinc oxide</td>
<td>Kashaya , Tikta Rasa</td>
<td>-----</td>
<td>Shia Virya</td>
<td>-----</td>
</tr>
</tbody>
</table>

• Total 10 Subjects who was showing high BSL Fasting >130mg/dl, pp>180mg/dl were selected from Kayachikitsa OPD of D. Y. Patil Ayurvedic Hospital, Nerul,Navi Mumbai. Yashad Bhasma (zinc ash) 125 mg +Triphala Churna 2 gms BD before Lunch and Dinner was given with warm water for three months. Data was recorded in CRF during regular monthly intervals.

INCLUSION CRITERIA:

1. Subjects with high BSL Fasting >130mg/dl, pp>180mg/dl were not selected for study.
2. Subjects having high Fasting blood sugar > 250 mg/dl were not selected for study.
3. Subjects having high Post Prandial blood sugar > 350 mg/dl were not selected for study.
4. Subjects having high HbA1c > 8 were not selected for study.
5. Subjects having known major complications of Diabetes like Ketoacidosis, Nephropathy, Neuropathy, Retinopathy, and Diabetic wounds.
6. Known cases of Severe/Chronic hepatic or renal disease.
7. Known subject of any active Malignancy.
8. Subjects giving history of significant Cardiovascular event < 40 weeks prior to study.
9. Subjects having known chronic infectious disease, such as active Tuberculosis, Hepatitis B or C, or HIV.
Criteria used for assessment of clinical symptoms of type II DM:
- Subjective Assessment –
The clinical symptoms marked in four grades-
0 – Absent ,1 – Mild ,2 –Moderate,3 – Severe
1. Polyuria: Gradation for Frequency of urination
a) grade 0 - 5-6 times in 24 hours
b) grade 1 - 7-9 times in 24 hours
c) grade 2 - 10-12 times in 24 hours
d) grade 3 - 13 or more times in 24 hours
2. Polydypsia: Gradation used for daily water consumption
a) grade 0 < 7 glasses
b) grade 1 - 8-9 glasses
c) grade 2 -10-12 glasses
d) grade 3 - More than 12 glasses.
3. Polyphagia: Gradation used for Daily Diet
a) grade 0 - 2 Meals (including Breakfast)
b) grade 1 - 3 Meals (including Breakfast)
c) grade 2 - 4 Meals (including Breakfast)
d) grade 3 - >4 Meals (including Breakfast)
4. Fatigue: Gradation used for Fatigue over the past week
a) grade 0 No fatigue feeling throughout the week.
b) grade 1 Fatigue feeling on 1-2 days during the week
c) grade 2 Fatigue feeling on 3-5 days during the week
d) grade 3 Fatigue feeling throughout the week

Study Type: Single arm, Prospective, Interventional clinical study.
Sample size: Total 10 subjects were enrolled for this study
Place of Clinical Study: D.Y.Patil School of Ayurveda Nerul Navi Mumbai

OBSERVATION AND RESULTS:
Statistical Analysis
Table 2 Wilcoxon matched-pairs signed-ranks test used to assess Subjective parameters in this study.

<table>
<thead>
<tr>
<th>Sr.No.</th>
<th>Characteristic</th>
<th>W</th>
<th>n</th>
<th>p</th>
<th>Inference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Polyuria</td>
<td>34.00</td>
<td>10</td>
<td>&lt;0.01</td>
<td>Very Significant</td>
</tr>
<tr>
<td>2</td>
<td>Polydypsia</td>
<td>35.00</td>
<td>10</td>
<td>&lt;0.01</td>
<td>Very Significant</td>
</tr>
<tr>
<td>3</td>
<td>Polyphagia</td>
<td>40.00</td>
<td>10</td>
<td>&lt;0.01</td>
<td>Very Significant</td>
</tr>
<tr>
<td>4</td>
<td>Fatigue</td>
<td>40.00</td>
<td>10</td>
<td>&lt;0.01</td>
<td>Very Significant</td>
</tr>
</tbody>
</table>

Table 3. Paired t-Test is used to compare Blood Sugar levels and HBA1c levels BT& AT

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Parameters</th>
<th>Mean</th>
<th>SD</th>
<th>SEM</th>
<th>t</th>
<th>p</th>
<th>Inference</th>
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<tbody>
<tr>
<td>1</td>
<td>FBS</td>
<td>BT</td>
<td>189.0</td>
<td>14.06</td>
<td>4.45</td>
<td>6.0337</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td></td>
<td>AT</td>
<td>162.20</td>
<td>21.10</td>
<td>6.67</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>PPBS</td>
<td>BT</td>
<td>205.70</td>
<td>16.72</td>
<td>5.29</td>
<td>6.1190</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td></td>
<td>AT</td>
<td>187.90</td>
<td>14.39</td>
<td>4.55</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>HbA1c</td>
<td>BT</td>
<td>6.850</td>
<td>0.303</td>
<td>0.096</td>
<td>5.2500</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td></td>
<td>AT</td>
<td>6.710</td>
<td>0.321</td>
<td>0.102</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Graph 1. FBS of subjects Before Treatment and After Treatment
Statistical analysis done with help of paired t test and Wilcoxon matched-pairs signed-rank test. The study showed reduction of FBS, PPBS, and HBA1C values before and after the trial at the level of significance $p < 0.01$.

**DISCUSSION:** Yashad bhasma is having Kashaya and Tikta Rasa and Shita Virya\(^{(4,5)}\) it is useful in Kapha pittaja Prameha, adding Triphala churna in it increases its properties and relieving Dhatushaithilya. People with diabetes may have lower serum zinc concentration. Zinc supplement improves glycemic control and decrease HbA1c percentage. Zinc also has protective effects for insulin secreting cells in the pancreas. Thus, it helps preventing further damage to the cells and improves health in diabetes. Triphala is a detoxifying agent and rejuvenator and Rasayana. Triphala is known to possess antidiabetic effect on oral administration and can improve glucose utilization In Prameha. Yashad
Yashadbhasma with Triphala Churna is significantly beneficial in management of Prameha Type II Diabetes Mellitus.

CONCLUSION: The study showed reduction of Objective and Subjective parameters at level of significance p<0.01. The Yashad bhasma with Triphala Churna was significantly effective in Type II Diabetes Mellitus. This combination also shows betterment of general health and enhancement of Bala and improvement in quality of life of type II Diabetes Mellitus patients. This was only a pilot study Yashad bhasma with Triphala churna combination should be tried on more number of patients.

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