ROLE OF VIRECHANA KARMA IN DIABETES MELLITUS TYPE 2: A CLINICAL TRIAL

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ABSTRACT

Diabetes is a major public health problem that is approaching epidemic proportions globally. It is the most common endocrine disorder with an increasing global prevalence and incidence. Type 2 diabetes is associated with a ten-year-shorter life expectancy. Diabetes Mellitus is aggravated by and associated with metabolic complications that can subsequently lead to premature death. The available drug therapy has good effects on levels of blood sugar but it has many side effects and also its dose increases with time, while Ayurveda not only gives efficient results on high blood sugar but also does not have any side effects. On behalf of blood sugar profile and BMI, the evaluation of Virechana Karma (medicated purgation therapy) was done in comparison to modern oral hypoglycemic and well-accepted drug Metformin. Total 40 patients of newly diagnosed cases of Diabetes Mellitus were taken and divided into two groups. As Trial group, 20 patients were given 2 sittings of Virechana Karma with study period of 60 days while in Control Group 20 patients were given tablet Metformin 500 mg O.D. for 60 days. Virechana is found to be more effective than Metformin. 75.86% reduction was found in Blood sugar F; 77.59% reduction in Blood sugar PP; 20.00% reduction in HbA1C and 65.00% reduction in BMI was found in Virechana group. So, Virechana karma has highly significant results in reducing blood sugar levels, HbA1c and BMI along with better follow up results.

Keywords: Diabetes Mellitus Type 2, Endocrine, Madhumeha, Ayurveda, Virechana Karma

INTRODUCTION

According to the official WHO data, India tops the list of countries with the highest number of diabetics1. Type 2 diabetes is a global public health crisis that threatens the economies of all nations, particularly developing countries. Fueled by rapid urbanization, nutrition transition and increasingly sedentary lifestyles, this epidemic has grown in parallel with the worldwide rise in obesity2.

Diabetes mellitus is a chronic disorder of carbohydrate, fat and protein metabolism. A relative or absolute deficiency in insulin secretory response, which translates into impaired carbohydrate (glucose) use, is a characteristic feature of Diabetes Mellitus, resulting in hyperglycemia3. It is one of the leading causes of morbidity and mortality. The International Diabetes Federation (IDF) estimates that by 2030, 8.4% of India's adult population will have diabetes and this figure is expected to go up to 101.1 million4. It is associated with long-term potentially catastrophic effects on almost all systems of the body5. It has turned out to be the biggest “silent killer” today in the world6. Four types of Diabetes Mellitus can be recognized viz. Type 1 (beta cell destruction, autoimmune/idiopathic), Type 2 (defect in insulin resistance or insulin secretion, impaired glucose tolerance), Type 3 (from specific etiology) and Type 4 (gestational). Type 1 accounts for 5-10% of all cases of diabetes however Type 2 diabetes mellitus accounts for 90-95% of all diagnosed diabetes cases7.

In Ayurveda, Diabetes mellitus is described under Madhumeha or Kshaudrameha, which literally means excessive urine with sweet taste like honey. Amongst the twenty types of Prameha described in Ayurveda, Madhumeha is caused by vitiation of Vata dosha and is a sub-type of Vatika Prameha. The Vata may be provoked either directly by its etiological factors, by Avarana of Kapha and Pitta to Vayu or by Dhatukshaya. Madhumeha has many clinical similarities to the modern day Diabetes mellitus8. Madhumeha is included in Ashtamaharoga (eight major disorders) by Acharya Charaka in Indriya sthana which indicates the graveness of this disease9. Acharya Sushruta also has given notable importance to this dreaded disease by giving a separate chapter on Madhumeha in Chikitsa sthana10. Diabetes Mellitus is aggressively progressive and the prognosis is poor unless definite measures are taken to control the disease. In spite of tremendous advancement of modern system of medicine i.e. oral hypoglycemic agent and insulin till date, an ideal therapy or drug which can treat diabetes is not yet available and still scientists are struggling to search an effective and safe remedy. Ayurveda can provide a rational treatment where it can prevent the disease without provoking new complaints. So an effort has been made here to search for the safe and effective treatment, without any side effects. Ayurveda can provide effective management for Madhumeha without hazardous side effects.

Acharya Sushruta has mentioned that in Madhumeha, the vitiated doshas remains situated in the lower part of the body owing to the inefficiency of various Dhamanis i.e. vessels11. Samshodhana (Bio cleansing therapy) is the best treatment for elimination of doshas. Vaghbha has mentioned that doshas should be eliminated through the nearest passage12. Under the Samprapti (pathogenesis) of Santarpanjanya Madhumeha, the vitiated Kapha and Pitta obstructs the path of Vata causing its provocation. Panchakarma treatment is a truly unique approach for revitalization, rejuvenation and prevention of various disorder which aims at the elimination of excessive doshas from the body to maintain the state of health for a longer duration. In case of Madhumeha, for the low lying doshas, Virechana is the appropriate Shodhana procedure, which is specific for the elimination of vitiated Pitta dosha as well as Kapha dosha. So in the present study, Virechana has been selected for the patients of Diabetes Mellitus.

Taking above considerations in mind, study is entitled, “Clinical evaluation of Virechana in Diabetes Mellitus Type 2". The effect
of Virechana in Diabetes Mellitus Type 2 was then compared with standard modern drug, Metformin.

AIM AND OBJECTIVE

To evaluate the efficacy of Virechana karma in the management of Diabetes Mellitus Type 2.

MATERIALS AND METHODS

This work has been ethically approved by our university and also enrolled in CTRI - CTRI/2018/02/011668 [Registered on: 02/02/2018] - Trial Registered Retrospectively

Patients have been selected on the basis of classical symptomatology of Diabetes Mellitus Type 2 from OPD and IPD of Department of Panchakarma, Hospital of Rishikul Campus, Uttarakhand Ayurveda University. Thereafter the patients were subjected for detailed clinical history & physical examination.

Criteria for Selection of Patients

(A) Inclusion Criteria

1. Patients having signs & symptoms of Diabetes Mellitus type 2.
2. Newly diagnosed cases of Diabetes Mellitus Type 2 (Maximum 1 year)
3. Fasting blood glucose level > 110 mg/dl
4. Post Prandial blood sugar level > 140 mg/dl
5. HbA1c > 6.0% or above 42 mmol/mol
6. Patients between the age group of 20-60 years irrespective of gender.
7. Patients eligible for Virechana karma.

(B) Exclusion Criteria

1. Patient with Diabetes Mellitus Type I.
2. Patients suffering from secondary diabetes.
3. Patients suffering from any severe systemic illness.
4. Hypertensive patient with B.P > 200/100 mm of Hg.
5. Patients suffering from Diabetogenic Renal complications.
6. Other contraindication for Virechana karma indicated in text.

Grouping Pattern

In each group 20 patients has been taken for trial.

Group A – Patients in this group will be administered with 2 sittings of Virechana procedure with the interval of 15 days.

- First Deepana-Pachana then Snahapana followed by administration of Virechaka Dravya used on the basis of Koshta, Prakriti and Agni of the patient.
- Then, Samsarjana karma was followed as per type of Shudhhi.

Group B - Control Group - 20 patients was treated with Metformin for 60 days in dose of 500mg once daily before meals with water.

RESULTS

As, it is a double group study to evaluate the effect of Virechana in the management of Diabetes Mellitus Type 2, there were no subjective parameters to make Diagnosis of Diabetes Mellitus Type 2. So, Only Objective parameters were taken for assessment of therapy.

Table 1: Statistical Analysis of Overall Effect of Virechana on the objective parameters of DM Type 2 in Group A. (Wilcoxon Signed Rank Test)

<table>
<thead>
<tr>
<th>Sample Size</th>
<th>Mean Difference</th>
<th>% Change</th>
<th>W</th>
<th>N</th>
<th>P</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Sugar F</td>
<td>2.20</td>
<td>75.86</td>
<td>-171</td>
<td>20</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>Blood Sugar PP</td>
<td>2.25</td>
<td>77.59</td>
<td>-190</td>
<td>20</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>HbA1C</td>
<td>0.55</td>
<td>20</td>
<td>-66</td>
<td>&lt;0.001</td>
<td>HS</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>0.65</td>
<td>65</td>
<td>-66</td>
<td>&lt;0.001</td>
<td>HS</td>
<td></td>
</tr>
</tbody>
</table>

Group A after Virechana karma

- The mean value of Blood sugar F reduced by 2.20 (75.86%) with extremely significant p value (<0.001).
- The mean value of Blood sugar PP reduced by 2.25 (77.59%) with extremely significant p value.
- The mean value of HbA1C reduced from 2.70 to 2.15 (20.00%) with extremely significant p value.
- BMI reduced from 1.0 to 0.35 with extremely significant p value.

Group B (Metformin)

- The mean value of Blood sugar F reduced by 1.55 (60.78%) with extremely significant p value (<0.001).
- The mean value of Blood sugar PP reduced by 1.85 (66.1%) with extremely significant p value.
- The mean value of HbA1C reduced by 0.45 (17.3%) with highly significant p value.
- BMI reduced from 0.70 to 0.25 (64.3%) with non-significant p value.

Table 2: Effect of Control Group (Group B) on objective parameters of DM Type 2 (Wilcoxon Signed Rank Test)

<table>
<thead>
<tr>
<th>Sample Size</th>
<th>Mean Difference</th>
<th>% Change</th>
<th>W</th>
<th>N</th>
<th>P</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Sugar F</td>
<td>1.55</td>
<td>60.78</td>
<td>-136</td>
<td>20</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>Blood Sugar PP</td>
<td>1.85</td>
<td>66.1</td>
<td>-120</td>
<td>20</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>HbA1C</td>
<td>0.45</td>
<td>17.3</td>
<td>-45</td>
<td>&lt;0.001</td>
<td>(0.004)</td>
<td>HS</td>
</tr>
<tr>
<td>BMI</td>
<td>0.45</td>
<td>64.3</td>
<td>-15</td>
<td>&gt;0.05</td>
<td>(0.063)</td>
<td>NS</td>
</tr>
</tbody>
</table>
the signs & symptoms of
in the liver and brings a state of equilibrium thereby
activity. Thus
of all enzymatic activit
Secondly,
Madhumeha
(immunity). Decrement of
Rakta
nourishment. Each and every cell gets nourished through
is beneficiary for the formation of
Firstly,
In
Illustration of
follow up results over all the objective parameters.
After one month, all the objective parameters shown slight
increment in both the groups, but Group A is found to have better
follow up results over all the objective parameters.

**DISCUSSION**

**Illustration of Therapeutic Efficacy of the Virechana karma**

In Madhumeha, the therapeutic efficacy of Virechana karma can be illustrated through two pathways.

Firstly, Virechana karma removes bahudrava shleshma and pitta from Vayu shhana which leads to Pradeepan of dhatwagni which in turn results in maintenance of Dosh-dhatu equilibrium which is beneficiary for the formation of Uttarottar dhatu and their nourishment. Each and every cell gets nourished through Rasa & Rakta dhatu which enhances the production of essence of dhatu Oja in the body which is responsible for vyadhikshamatva (immunity). Decrement of Oja is the major casualty in Madhumeha which gets corrected through Virechana.

Secondly, Virechana directly acts on Liver which is the main site of all enzymatic activities thereby increasing the metabolic activity. Thus Virechana corrects the mal-production of glucose in the liver and brings a state of equilibrium thereby suppressing the signs & symptoms of Madhumeha (DM Type 2).

**Blood sugar Fasting** - Virechana was found more effective in lowering blood sugar fasting values by 0.65 as compared to results in group B which was found statistically non-significant. **Blood sugar PP**- Results obtained in group A were better as compared to group B by 0.40 which is statistically non-significant in comparison. **HbA1C**- Group A showed more effective results by 0.10 with non-significant p value.

**BMI**- Group A was found more effective by 0.20 which is statistically non-significant.

**Overall assessment of therapy**

The overall assessment of all the therapies was decided on the basis of improvement in biochemical parameter (blood glucose level). The percentage improvement of Blood sugar F, Blood sugar PP, HbA1C and BMI was calculated for assessment.

Table 3: Intergroup Comparison (Mann U Whitney Test)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group</th>
<th>N</th>
<th>Mean Rank</th>
<th>Sum of Ranks</th>
<th>Mann Whitney U</th>
<th>P-Value</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Sugar F</td>
<td>Group A</td>
<td>20</td>
<td>2.200</td>
<td>478</td>
<td>132</td>
<td>0.0664</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>20</td>
<td>1.550</td>
<td>342</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>40</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Sugar PP</td>
<td>Group A</td>
<td>20</td>
<td>2.250</td>
<td>446.5</td>
<td>163.5</td>
<td>0.3252</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>20</td>
<td>1.850</td>
<td>373.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>40</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1C</td>
<td>Group A</td>
<td>20</td>
<td>0.5500</td>
<td>430</td>
<td>180</td>
<td>0.5909</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>20</td>
<td>0.4500</td>
<td>390</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>40</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>Group A</td>
<td>20</td>
<td>0.6500</td>
<td>453</td>
<td>157</td>
<td>0.2414</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>20</td>
<td>0.4500</td>
<td>367</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>40</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**FOLLOW UP**

Table 5: Follow up results after one month of completion of treatment

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group A</th>
<th>After 1 month</th>
<th>Group B</th>
<th>After 1 month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Sugar F</td>
<td>112.0</td>
<td>113.74</td>
<td>117.46</td>
<td>124.584</td>
</tr>
<tr>
<td>Blood Sugar PP</td>
<td>139.33</td>
<td>142.805</td>
<td>143.17</td>
<td>146.69</td>
</tr>
<tr>
<td>HbA1C</td>
<td>6.9</td>
<td>6.71</td>
<td>7.425</td>
<td>7.23</td>
</tr>
<tr>
<td>BMI</td>
<td>23.735</td>
<td>23.935</td>
<td>22.91</td>
<td>23.14</td>
</tr>
</tbody>
</table>

**Samprapti Vighatan**

Virechana effect at Dosh level- Virechana is told as the best treatment of Pitta but it is also a treatment of Kapha Dosa esp. which is situated in Pitta shhana. Kapha Dosa has similar property to that of Meda Dhatu & Kleda, which is major Dushya involved in the pathology of Madhumhe.

**Effect at Dhatu level**- According to Acharya Charaka, all the Poorvarupa in Prameha roga is due to Meda dhatu pradushhti and Acharya Kashyapa mentioned that Shuddhi of Saptadhatus take place with the Virechana karma. Hence in majority of the Dhatu pradoshaja Vikaras, Virechana karma is more beneficial.

**Effect at Ama and Agni**- As it is a disorder arising due to vitiation of Agni mainly, Dhatwagni. Virechana removes Avarana of Vayu in Kostha. It also corrects the Medo Dhatwagni. Therefore, the formation of Uttarottar dhatu is increased, while the formation of Meda & Kleda is decreased.

**Effect at Srotas level** - Mutravaha, Udakavaha, Medovaha Vaigunya are involved in pathogenesis of Madhumhe which will be corrected by Virechana. So, by breaking pathology at Srotas level it pacifies the disease.

**Effect as Aptarpaka Chikitsa**- Madhumhe is a Santarpanjanya Vyadhi. Virechana karma is mentioned in the treatment of
Santarpanjanya Vyadh. It also flushes out excessive Ambu Dhatu which is one of the dushayas in Madhuhema.

**Effects of Virechana on Blood Glucose Level** - Bahu Drava Sleshma & Bahu abaddha Meda is the Dosa Vishesha & Dushya Vishesha of Madhuhema (DM Type 2). Bahudrava sleshma can be some sort of target tissue defect, whereas Bahu-abaddha meda can be correlated with free fatty acids, which are released from intra-abdominal central adipose tissues. Free fatty acids may cause insulin resistance. Virechana is found to be to be highly effective in correcting obesity and thus reduces the level of free fatty acids.

As role of Virechana is on the site of Pitta, it can be assumed that by acting primarily on liver and pancreas, it may help to reduce hepatic glucose production and overcome the impaired insulin secretion. Both of these can justify its role in reducing both FBS and PPBS significantly as found in the present study. Also increased lipolysis, elevated free fatty acid levels, along with accumulation of intermediary lipid metabolites contributes to further increase glucose output, reduce peripheral glucose utilization, and impair beta-cell function.

Virechana directly or indirectly corrects the whole metabolism of lipid formation and excretion thus normalizing beta-cell dysfunction. Beta cell of islets of Langerhans get dysfunctional due to Cytotoxic T cells, Natural killer lymphocytes and Nitric oxide (NO). The products of metabolism can be eliminated by shodhana karma (purification) as described by terms like Malapaham (excretion of toxins) and Visudha koshtha (clearing the gastrointestinal tract). The cleansing therapies therefore might reduce immune-inflammatory processes that have been implicated in dysfunction of Beta cells of Islets of Langerhans, thereby harmonizing their functioning.

**CONCLUSION**

Thus it can be concluded that Diabetes Mellitus Type 2 can be co-related to Prameha and Madhuhema. This disease is clearly explained in Ayurveda. Less physical activity and positive family history were observed to be linked with the disease. Virechana karma has highly significant results in reducing blood sugar levels, HbA1c and BMI.

Standard drug (Metformin) had a little less effect on blood glucose levels and non-significant result on BMI but this difference is statistically not significant when compared to Virechana. Virechana have a much better effect on BMI, it proves its better effect on insulin resistance. During follow up study it was observed that the effect produced by Virechana persist more than that of standard drug. Both the group shown slight increment in all the objective parameters but Group A is found to have better follow up results. Thus Virechana can be used for the effective and safe management for newly diagnosed cases of Diabetes Mellitus Type 2.

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**REFERENCES**


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