A Clinical Study on the Efficacy of Haridradi Kashaya in the Management of Madhumeha (Type 2 Diabetes Mellitus)

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ABSTRACT
According to Diabetes Atlas 2017, 8th edition, published by International Diabetes Federation, Diabetes is one of the largest global health emergencies of the 21st century. There are 425 million people estimated to have diabetes in 2017, which will be estimated 629 million in 2045 in the age group of 20-79 years. Madhumeha is one among the VatajaPrameha that has been considered as a mahagada and sequel of all varieties of Prameha. As per AcharyaCharaka in case of Madhumeha along with mutra there is excretion of Ojha which is madhura in nature. Madhumeha may be correlated with Diabetes Mellitus. Though different herbal compound has been described in Ayurvedic classics, more research and clinical evaluation are going on to establish Ayurvedic medicine as an effective treatment of Madhumeha (Type 2 Diabetes Mellitus). The present clinical study was on the efficacy of HaridradiKashaya (Curcuma longa, Berberis aristata, Embelia ribes and Valeriana wallichii) in the management of Madhumeha which is explained in Charak Samhita, Chikitsa Sthan, Chapter 6, sloka 27. This open clinical trial study was conducted on 100 patients, out of which 84 patients completed the study. The duration of study was 90 days and follow up was taken after 15 days. The results were prepared as per statistical analysis and the result shows that HaridradiKashaya is a potent drug in the management of Madhumeha.

KEYWORDS
Prameha, Madhumeha, Ojha, HaridradiKashaya
INTRODUCTION
As the birds are attracted towards the trees where their nest lies, similarly Prameha affects the persons who are voracious eaters, less enthusiastic physically as well as mentally, over corpulent and over unctuous. Acharya Charaka has mentioned that indulgence in the etiological factors results in the aggravation of Kapha, Pitta, Meda and Mamsa & obstruct the normal pathway of Vata. Aggravated Vata carries the Ojha to the Basti resulting in the illness. He also has mentioned that Madhumeha is one among the VatajaPrameha that has been considered as Mahagada. Again Sushruta has mentioned in his text that Madhumeha is a variety of VatajaPrameha, which is referred to as sequel of all varieties of Prameha. As per Acharya Charaka in case of Madhumeha along with mutra there is excretion of Ojha which is madhura in nature. Due to this madhurata the ants get attracted towards this type of mutra. So, Madhumeha may be correlated with Diabetes Mellitus.

Diabetes mellitus refers to a group of common metabolic disorders that share the phenotype of hyperglycemia. Depending on the etiology of the Diabetes mellitus, factors contributing to hyperglycemia include reduced insulin secretion, decreased glucose utilization and increased glucose production. According to diabetes atlas 2017, 8th edition published by International Diabetes Federation, Diabetes is one of the largest global health emergencies of the 21st century. There are 425 million people estimated to have diabetes in 2017, which will be estimated 629 million in 2045 in the age group of 20-79 years. Approximately, 4.0 (3.2-5.0) million people aged between 20 and 79 years are estimated to die from diabetes in 2017 which is equivalent to one death every eight seconds. This is higher than the combined number of deaths from infectious diseases. [1.1 million deaths from HIV/AIDS, 1.8 million from tuberculosis and 0.4 million from malaria in 2015].

India which is presently in the second position among the top ten countries after China with 72.9 million people of the age group of 20-79 years are estimated to have diabetes in 2017, which is estimated to be 134.3 million in 2045 and thus India will become the top most country in the tally. Increasing incidence of Madhumeha become a burning challenge for Ayurvedic Physicians to search for an effective treatment. Though different herbal
compound have been described in Ayurvedic Classics but lot of research and clinical evaluation are going on to establish Ayurvedic medicines as an effective treatment for Madhumeha. The present study is focused on clinical study on the efficacy of HaridradiKashaya (Haridra, Daruharidra, Vidanga and Tagar) in the management of Madhumeha (Type2 Diabetes Mellitus). HaridradiKashaya is mentioned in Charak Samhita, Chikitsa Sthan, Chapter 6, sloka 27.

AIMS & OBJECTIVES
1. To study the clinical effect of Haridradi Kashaya (prepared of Haridra, Daruharidra, Vidanga and Tagar) in the management of Madhumeha (Type2 Diabetes Mellitus).
2. To find out an effective, low cost and safe remedy to combat the disease.

MATERIAL & METHODS
SELECTION OF PATIENTS:
Total 100 patients of either sex diagnosed to be suffering from Madhumeha were selected randomly fulfilling inclusion and exclusion criteria attending OPD and IPD of the Dept. of Kayachikitsa of Govt. Ayurvedic College & Hospital, Guwahati-14.

PRE-TREATMENT OBSERVATION:
After taking the consent of the patient, the study was carried out along with the registration and necessary information. After preliminary registration diagnostic medical history was taken according to both Ayurvedic and Modern clinical methods.

DIAGNOSTIC CRITERIA:
Initial diagnosis of Madhumeha (Type 2 Diabetes Mellitus) was typically based on the patient’s general complains with sign and symptoms indicating towards Madhumeha along with assessment of sugar level in blood after fasting, PP and Glycosylated Hemoglobin (HbA1C).

INCLUSION CRITERIA
1. Males and females belonging to age group between 30 -70 yrs.
2. Newly diagnosed cases of Madhumeha (Type 2 Diabetes Mellitus).
3. Patient already on oral hypoglycemic drug for over a year.

EXCLUSION CRITERIA
1. Patient taking regular insulin/secondary diabetic (Cushing’s syndrome, Acromegaly, glucocorticoid induced etc)
2. Malignancy, Tuberculosis patient
3. Pregnant women
4. Surgical interventions
5. Patient with severe cardiac problem
6. Patient with significant renal and hepatic impairment.
LABORATORY INVESTIGATIONS

1. Fasting Blood Sugar (FBS)
2. Postprandial Blood Sugar (PPBS)
3. Glycosylated Hemoglobin (HbA1C)
4. Urine-sugar

STUDY DESIGN

A single clinical trial.

SAMPLE SIZE: Total number of 100 patients registered

DROP OUTS: 16

DURATION OF TREATMENT: 90 days

FOLLOW UP: At 15 days interval x 6 follow up.

SOURCE OF FORMULATION:
The Yavakuta Churna of Haridradi Kashaya was prepared in the State Ayurvedic Pharmacy, Govt. Ayurvedic College & Hospital, Guwahati-14.

INTERVENTIONS:
The Haridradi Kashaya (Haridra, Daruharidra, Vidanga and Tagar) was given in a dose of 25ml (12.5 gm in 200 ml water reduced to 25ml) before meal twice in a day for 3 months. (Table1)

CRITERIA FOR ASSESSMENT:
1. Improvement in sugar level for both fasting and PP (After every 15 days and at the end of complete trial).
2. Improvement in HbA1C at the end of 3 months.

<table>
<thead>
<tr>
<th>Sanskrit</th>
<th>Botanical</th>
<th>Part</th>
<th>Qty.</th>
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</thead>
<tbody>
<tr>
<td>Haridra</td>
<td>Curcuma longa linn</td>
<td>Rhizome</td>
<td>1 part</td>
</tr>
<tr>
<td>Daruharidra</td>
<td>Berberis aristata</td>
<td>Root</td>
<td>1 part</td>
</tr>
<tr>
<td>Vidanga</td>
<td>Embelia ribes burm</td>
<td>Seed</td>
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<tr>
<td>Tagar</td>
<td>Valeriana wallichit</td>
<td>Root</td>
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ETHICAL CLEARANCE

The prior consent of the patients was taken before administrating the drug by fulfilling the conditions as per IEC (Institutional Ethical Committee).

IEC/16 20-122 Dated 9/5/16

OBSERVATIONS AND RESULTS

A total of 100 patients were enrolled for the present study out of which 16 patients dropped out leaving 84 patients for the study. Maximum number of patients in this study, i.e. 38.09% belonged to the age group of 41 to 50 yrs, 53.57% patients male and 69% Hindus, majority number of patients i.e., 44.05% had completed their secondary/H.S.L.C. education, 30.95% patients were household, 57.14% belonged to lower middle socioeconomic status, most of the patients i.e., 84.52% were married, 53.57% were Urban, 32.14% had the disease for less than 1 year, 51.19% had positive family history, 94.04% patients were on non-vegetarian diet, maximum patients i.e., 55.95% were overweight with...
BMI in between (25-29.9), 45.23% patients were addicted to betel nut/tobacco, 70.23% of patients were with mild physical activity, 36.90% of patients were having hypertension as an associated complication.

1) Effect of Trial Drug on FBS:
The initial mean ± SD of FBS level was 171.2±50.77 which was reduced to 153.1±45.93 after 15 days, 150.7±42.39 after 30 days, 143.5±37.31 after 45 days, 139.3±31.36 after 60 days, 131.3±29.64 after 75 days and 124.4±27.01 after 90 days respectively. The reduction of FBS after 15 days & 30 days is statistically significant and after 45 days, 60 days, 75 days & 90 days is statistically highly significant. It implies that the effect of the trial drug on FBS after 90 days i.e., after treatment is highly significant. (Table 2, Figure 1).

Table 2 Effect of Trial Drug on FBS

<table>
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<tr>
<th>N=84</th>
<th>BT</th>
<th>FU1</th>
<th>BT-FU1</th>
<th>F/U2</th>
<th>BT-FU2</th>
<th>F/U3</th>
<th>BT-FU3</th>
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<th>F/U5</th>
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<td>153.1</td>
<td>150.7</td>
<td>143.5</td>
<td>139.3</td>
<td>131.3</td>
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<td>SD</td>
<td>50.77</td>
<td>45.93</td>
<td>42.39</td>
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<td>6.51</td>
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</table>

![EFFECT OF TRIAL DRUG ON FASTING BLOOD SUGAR](image)

Fig 1 Effect of Trial Drug on FBS

2) Effect of Trial Drug on PPBS:
The initial mean ± SD of PPBS level was 267.2±69.85 which was reduced to 239.2±62.71 after 15 days, 223.2±60.14 after 30 days, 206.3±52.74 after 45 days, 197.9±45.32 after 60 days, 189.5±43.56 after 75 days and 179.5±34.98 after 90 days. The reduction of PPBS after 15 days is statistically significant and after 30 days, 45 days, 60 days, 75 days & 90 days is statistically highly significant. It implies that the effect of the trial drug on PPBS after 90 days i.e., after treatment is highly significant. (Table 3, Figure 2)
Fig 2 Effect of Trial Drug on PPBS

3) Effect of Trial Drug on Glycosylated Hemoglobin (HbA1c):

Mean Glycosylated Hemoglobin (HbA1c) before treatment was 8.76 which decreased by 7.03 and SD from 1.72 to 0.59. Z=9.10, P<0.001; hence the result is statistically highly significant. It implies that the effect of the trial drug on Glycosylated Hemoglobin (HbA1c) after 90 days i.e. after treatment is highly significant. (Table 4, Figure 3).

Table 4 Effect of Trial Drug on Glycosylated Hemoglobin (HbA1c)

<table>
<thead>
<tr>
<th>N</th>
<th>Mean BT</th>
<th>SD BT</th>
<th>SE</th>
<th>Z value</th>
<th>P value</th>
<th>Remarks</th>
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</thead>
<tbody>
<tr>
<td>84</td>
<td>8.76</td>
<td>1.72</td>
<td>.59</td>
<td>9.10</td>
<td>P&lt;0.001</td>
<td>Highly significant</td>
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</table>

CONCLUSION

It can be concluded that Haridradi Kashaya as mentioned in Charak Samhita, Chikitsa Sthan, Chapter 6, sloka 27 is effective in the management of Madhumeha and has got hypoglycemic effect. No untoward effect was noted during treatment and follow up period and patient satisfaction was also noted. Though this study is a preliminary study as a part of the educational research programme with limited number of patients in a fix stipulated time. In order to establish the hypoglycemic effect of this drug, a broad

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spectrum clinical and experimental study is required with the application of new technology to establish its effect in view of modern and scientific approach.

**Fig 3** Effect of Trial Drug on Glycosylated Hemoglobin (HbA1c)
REFERENCES

1. Charaka Samhita, Ayurvedadipika commentary, Dr. Lakshmidhar Dwivedi, Dr. B.K. Dwivedi & Dr. Pradip Kumar Goswami, 2014, Chowkhamba Krishnadas Academy, Nidan Sthana 4/50 pp.-712.

2. Charaka Samhita, Ayurvedadipika commentary, Dr. Lakshmidhar Dwivedi, Dr. B.K. Dwivedi & Dr. Pradip Kumar Goswami, 2016, Chowkhamba Krishnadas Academy, Sutra Sthana 17/78-80 pp.-362.

3. Charaka Samhita, Ayurvedadipika commentary, Dr. Lakshmidhar Dwivedi, Dr. B.K. Dwivedi & Dr. Pradip Kumar Goswami, 2014, Chowkhamba Krishnadas Academy, Indriya Sthana 9/8 pp.-1234.


5. Charaka Samhita, Ayurvedadipika commentary, Dr. Lakshmidhar Dwivedi, Dr. B.K. Dwivedi & Dr. Pradip Kumar Goswami, 2014, Chowkhamba Krishnadas Academy, Nidan Sthana 4/37 pp.-710.


7. Charaka Samhita, Ayurvedadipika commentary, Dr. Lakshmidhar Dwivedi, Dr. B. K. Dwivedi & Dr. Pradip Kumar Goswami, 2016, Chowkhamba Krishnadas Academy, Chikitsa Sthana 6/27 pp.-266.