CLINICAL STUDY TO EVALUATE EFFECT OF MUSTADI KWATH IN MADHUMEHA

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ABSTRACT

The dissertation is entitled “Clinical study to evaluate the effect of Mustadi kwath in Madhumeha. Diabetes mellitus has become a dreadful disease in the era. It is also described in Ayurvedic text in terms of Madhumeha. Diabetes Mellitus is a group of metabolic disease in which there are high blood sugar levels over a prolonged period, this high blood sugar produces the symptoms of frequent urination, increased thirst, and increased hunger. Untreated, diabetes can cause many complications. Sedentary lifestyle, lack of exercise, improper medication and urbanization precipitates the disease. In the present study, Mustadi kwath (mentioned in Bhaiyiya Ratnavali) was selected for clinical trial. The study comprises of 40 patients of Madhumeha. These patients were randomly selected on the basis of inclusion and exclusion criteria with detailed clinical history, physical examination and other desired investigation. The duration of study is of 90 days with 15 days follow up. After evaluating therapy it was observed that the ‘Mustadi kwath’ provided better relief to the patients of Madhumeha.

KEYWORDS: Madhumeha, Diabetes Mellitus, Mustadi kwath.

INTRODUCTION

Diabetes mellitus is a group of metabolic disease characterized by hyperglycemia resulting from defects in insulin secretion, insulin action or both. The chronic hyperglycemia of diabetes is associated with long term damage, dysfunction and failure of various organs, especially the eyes, kidneys, nerves, heart and blood vessels. Diabetes is worldwide in distribution and the incidence of both types of diabetes, i.e., type 1 and type 2 is rising. However, the prevalence of both varies considerably in different parts of the world and this is probably due to differences in genetic and environmental factors. The prevalence of both types in Britain is between 1 and 2% but almost 50% of cases of type 2 diabetes remain undetected. The great majority of cases seen worldwide have primary diabetes, and in Europe and North America the ratio of type 2: type 1 is approximately 7:3.[1]

According to the international Diabetes Federation there are currently 415 million people living with diabetes and the total is expected to rise to 640 million by 2040.[2]

There is a similar condition in Ayurveda, in which a person passes honey like (sweet) urine. And this is known as Madhumeha. Madhumeha is one among 20 types of Prameha (urological disorder) described in various Ayurvedic classics viz. Charak Samhita Sushruta Samhita, Ashtanga Sangraha, Madhav Nidan. Ancient seers have narrated that excess use of Guru (heavy to digest), Snigdha (unctuous), Amla (sour), and Nava (salt), Navanna (food prepared from newly harvested grains), new wine, Asya sukha (sedentary lifestyle), Atinidra (excess sleep), Avayama (lack of exercise), obtaining from Samshodhana (purification) therapy as the major causes of Madhumeha. All these factors (Nidan) leads to imbalance of Doshas, causes Manda- Agni and formation of Amadosh which increases Kleda, and also leads to Margavaran. Aggravated Vata brings Kleda and Oja to the Basti and ultimately produces profuse and turbid urination. This clinical presentation is termed as Madhumeha in Ayurveda.[3]

Ayurveda is non- invasive, cost effective and safe form of treatment. It has been proved as an ideal approach which not only aims diseased person, but also promotes health of a person. So that he may live a healthy and blissful life. This holistic science also described definition of ideal therapy or treatment. It explains that it is not coherent treatment in which medicine modifies the disease only but gives rise to new complication. In Ayurveda classics ‘Madhumeha’ is described as ‘Asadhya’ Vyadi and it cannot be cured totally but controlled definitely.[4]
AIMS AND OBJECTIVE
To evaluate the effect of Mustadi kwath in Madhumeha.

MATERIALS AND METHODS

Study design- Randomized Sampling, Single blind.

Source of Data- 40 patients of Madhumeha were selected for study from O.P.D/I.P.D. unit of P.G. department of Kayachikitsa, Uttarakhand Ayurveda University Gurukul Campus, Haridwar.

Sample size- 40

Duration of study- 90 days

Selection of drug- Mustadi kwath

Dose- 30ml BD before meal

Ingredients

| Contents | Part used | Part |
|----------|-----------|------|
| Musta    | Mool (root) | 1 |
| Amalki   | Phal (fruit) | 1 |
| Haritiki | Phal (fruit) | 1 |
| Vibhitak | Phal (fruit) | 1 |
| Indrayan | Mool (root) | 1 |
| Haridra  | Kand (stem) | 1 |
| Devdaru  | Twak (bark) | 1 |
| Murva    | Mool (root) | 1 |
| Lodhra   | Twak (bark) | 1 |

Inclusion Criteria
- Fasting blood glucose level>110mg/dl-<350mg/dl
- Post prandial blood sugar level>140mg/dl-<450mg/dl
- Patients between the age group of 30-60 years

Exclusion Criteria
- Patients of type1 diabetes mellitus
- Age below 30 years and above 60 year.
- Blood sugar- fasting blood sugar level>350mg/dl.
- Post Prandial blood sugar level>450mg/dl.
- Patients having complications.
- Patients suffering from any serious medical or surgical illness
- Personal matters

Criteria for Withdrawal
- Aggravation of complaints
- Inter current illness
- Any other difficulties

Subjective Parameters
- Prabhuta mutrata
- Avila mutrata
- Atisudha
- Daurbalaya
- Pipasaadhiyka
- Kar-padha daha

Objective Parameters
- Blood sugar fasting
- Blood sugar post-prandial
- HbA1c
- Bodyweight
- B.M.I

Investigations
- Hb%, TLC, DLC, ESR
- Lipid profile
- LFT
- Urine examination
- Urine sugar
- Body weight
- BMI

Grading of Symptoms

1. Prabhuta mutrata (Frequency of urine)
   - Urination 3-5 times per day, no or rarely at night-0
   - Urination 6-8 times per day, and 1-2 times per night- 1
   - Urination 9-11 times per day, and 3-4 times per night- 2
   - Urination >11times per day, and > 4times per night- 3

2. Pipasa - adhika (Polydipsia)
   - Feeling of thirst 7-9 times/24 hours, consuming 0, 1.5-2.0 litre/24 hour
   - Feeling of thirst 9-11 times/24 hours, consuming 1, 2.0-2.50 litre/24 hours
   - Feeling of thirst 11-13 times/24 hours, consuming 2, 2.5-3.00 litre/24 hours
   - Feeling of thirst >13 times/24 hours, consuming >3, >3.00 litre/24 hours

3. Avila mutrata (Turbidity in Urine)
   - Crystal clear fluid- 0
   - Faintly cloudy or hazy with slight turbidity- 1
   - Turbidity clearly present and newsprint easily read- 2 through test tube
   - Newsprint not easily read through test tube-3
   - Newsprint cannot be visualized through test tube-4

4. Kshudha- adhika (polyphagia)
   - As usual/ routine- 0
   - Slightly increased (extra 1-2 meals)- 1
   - Moderately increased (extra 3-4 meals)- 2
   - Markedly increased (extra 5-6 meals)- 3
5. **Daurbalya (Weakness)**
- No weakness in doing routine work and exercise- 0
- Mild weakness in doing routine work and exercise- 1
- Moderate weakness in doing routine work and exercise- 2
- Severe weakness in doing routine work and exercise- 3

6. **Kara-pada daha**
- No Daha- 0
- Mild Kara-Pada daha for short period- 1

**Statistical Analysis**

Wilcoxon signed rank test was applied on subjective parameters. Paired t test was applied on the both objectives and biochemical parameters. Thus, the obtained results were interpreted as:

- p>0.05 - Not significant
- P<0.01 and <0.05 - Significant
- P<0.001 – Highly significant

**OBSERVATIONS**

**Table 1.1:** Shows Status of 40 patients of Madhumeha

| Drug         | Total registered | Lama | completed |
|--------------|-----------------|------|-----------|
| Mustadi kwath| 40              | 0    | 40        |

**Table 1.2:** Shows the effect of Mustadi Kwath in Subjective Parameters

| Subjective Parameters | Mean | Median | SD | Wilcoxon W | P-Value | % Effect | Result |
|-----------------------|------|--------|----|------------|---------|----------|--------|
| Prabhu Mutrata        | 2.10 | 0.33   | 2.50 | 0.00 | 1.10 | 0.47 | -5.246 | a 0.00000016 | 84.52 | Sig |
| Pipasa Adhika         | 1.53 | 0.15   | 2.00 | 0.00 | 1.11 | 0.36 | -4.879 | a 0.00000107 | 90.16 | Sig |
| Avila Mutata          | 2.03 | 0.10   | 2.00 | 0.00 | 1.19 | 0.44 | -5.215 | a 0.0000018 | 95.06 | Sig |
| Kshudha Adhika        | 0.78 | 0.05   | 1.00 | 0.00 | 1.10 | 0.22 | -3.573 | a 0.00053240 | 93.55 | Sig |
| Daurbalya             | 1.70 | 0.53   | 2.00 | 0.00 | 1.18 | 0.60 | -4.724 | a 0.0003231 | 69.12 | Sig |
| Kara-Pada-Daha        | 0.73 | 0.25   | 1.00 | 0.00 | 0.82 | 0.54 | -3.578 | a 0.00034662 | 65.52 | Sig |

**Table 1.3:** Shows the effect of Mustadi Kwath in Objective Parameters

| Objective Parameters | Mean | N  | SD  | SE  | t-Value | P-Value | Result |
|----------------------|------|----|-----|-----|---------|---------|--------|
| Body Weight          | BT   | 69.55 | 40 | 8.47 | 1.34 | 1.677 | 0.102 | NS    |
|                      | AT   | 67.48 | 40 | 8.69 | 1.37 |        |        |       |
| BMI                  | BT   | 25.15 | 40 | 2.53 | 0.40 | 2.008 | 0.052 | NS    |
|                      | AT   | 24.35 | 40 | 2.88 | 0.46 |        |        |       |
| Blood Sugar Fasting  | BT   | 179.76 | 40 | 58.67 | 9.28 | 9.178 | 0.000 | Sig   |
|                      | AT   | 111.22 | 40 | 25.52 | 4.03 |        |        |       |
| Post Prandial        | BT   | 266.94 | 40 | 84.63 | 13.38 | 8.645 | 0.000 | Sig   |
|                      | AT   | 160.98 | 40 | 31.55 | 4.99 |        |        |       |
| HBAIC                | BT   | 9.74  | 40 | 1.41 | 0.22 | 9.779 | 0.000 | Sig   |
|                      | AT   | 8.05  | 40 | 1.07 | 0.17 |        |        |       |

**Table 1.4:** Shows the effect of Mustadi Kwath in Biochemical Parameters

| Objective Parameters | Mean | N  | SD  | SE  | t-Value | P-Value | Result |
|----------------------|------|----|-----|-----|---------|---------|--------|
| HB%                  | BT   | 14.32 | 40 | 1.63 | 0.26 | 1.752 | 0.088 | NS    |
|                      | AT   | 14.89 | 40 | 1.70 | 0.27 |        |        |       |
| TLC                  | BT   | 7566.50 | 40 | 1626.74 | 257.21 | 0.829 | 0.412 | NS    |
|                      | AT   | 7406.65 | 40 | 1566.25 | 247.65 |        |        |       |
| Neutrophil | BT  | 58.99 | 40   | 11.20 | 1.77 | -0.679 | 0.501 | NS    |
|-----------|-----|--------|------|-------|------|---------|-------|-------|
|           | AT  | 60.16  | 40   | 10.57 | 1.67 |          |       |       |
| Lymphocytes | BT | 30.11  | 40   | 7.24  | 1.14 | -0.815  | 0.420 | NS    |
|           | AT  | 31.03  | 40   | 9.76  | 1.54 |          |       |       |
| Monocytes | BT  | 2.33   | 40   | 2.51  | 0.40 | 0.308   | 0.760 | NS    |
|           | AT  | 2.25   | 40   | 2.07  | 0.33 |          |       |       |
| Basophils | BT  | 0.20   | 40   | 0.41  | 0.06 | -1.000  | 0.323 | NS    |
|           | AT  | 0.25   | 40   | 0.44  | 0.07 |          |       |       |
| Eosinophils | BT | 2.95   | 39   | 1.26  | 0.20 | -2.919  | 0.006 | Sig   |
|           | AT  | 3.21   | 39   | 1.28  | 0.21 |          |       |       |
| E.S.R     | BT  | 18.17  | 40   | 8.63  | 1.36 | 1.677   | 0.102 | NS    |
|           | AT  | 16.65  | 40   | 6.01  | 0.95 |          |       |       |

### Objective Parameters

| Objective Parameters            | Mean | N  | SD  | SE  | t-Value | P-Value | Result |
|---------------------------------|------|----|-----|-----|---------|---------|--------|
| Serum Cholesterol               | BT   | 188.43 | 40   | 43.20 | 6.83 | 0.381 | 0.705 | NS    |
|                                  | AT   | 186.26 | 40   | 39.22 | 6.20 |          |       |       |
| Serum Triglyceries              | BT   | 134.24 | 40   | 91.32 | 14.44 | 0.532 | 0.598 | NS    |
|                                  | AT   | 137.61 | 40   | 81.77 | 12.93 |          |       |       |
| HDL Cholesterol                 | BT   | 50.97  | 40   | 14.71 | 2.33 | 2.008 | 0.052 | NS    |
|                                  | AT   | 47.87  | 40   | 13.51 | 2.14 |          |       |       |
| VLDL                            | BT   | 27.02  | 40   | 18.19 | 2.88 | 0.423 | 0.674 | NS    |
|                                  | AT   | 27.52  | 40   | 16.51 | 2.61 |          |       |       |
| LDL Cholesterol                 | BT   | 116.78 | 40   | 25.20 | 3.98 | 0.560 | 0.578 | NS    |
|                                  | AT   | 118.42 | 40   | 25.53 | 4.04 |          |       |       |
| Total/HDL Cholesterol Ratio     | BT   | 4.02   | 40   | 1.41  | 0.22 | -1.108 | 0.275 | NS    |
|                                  | AT   | 4.19   | 40   | 1.41  | 0.22 |          |       |       |
| LDL/HDL Cholesterol Ratio       | BT   | 2.43   | 40   | 0.99  | 0.16 | -2.004 | 0.052 | NS    |
|                                  | AT   | 2.62   | 40   | 0.78  | 0.12 |          |       |       |

### Objective Parameters

| Objective Parameters            | Mean | N  | SD  | SE  | t-Value | P-Value | Result |
|---------------------------------|------|----|-----|-----|---------|---------|--------|
| Serum Bilirubin                 | BT   | 0.70  | 40   | 0.37 | 0.06 | -3.334 | 0.002 | Sig   |
|                                  | AT   | 0.88  | 40   | 0.41 | 0.06 |          |       |       |
| Conjugated                      | BT   | 0.30  | 39   | 0.17 | 0.03 | -2.358 | 0.024 | Sig   |
|                                  | AT   | 0.35  | 39   | 0.16 | 0.03 |          |       |       |
| SGOT/AST                        | BT   | 25.09 | 40   | 7.36 | 1.16 | 0.586 | 0.561 | NS    |
|                                  | AT   | 24.62 | 40   | 9.11 | 1.44 |          |       |       |
| SGPT/ALT                        | BT   | 24.32 | 40   | 8.76 | 1.38 | 0.026 | 0.979 | NS    |
|                                  | AT   | 24.30 | 40   | 8.77 | 1.39 |          |       |       |
| Alkaline Phosphate              | BT   | 108.82 | 40   | 34.27 | 5.42 | 1.814 | 0.077 | NS    |
|                                  | AT   | 104.03 | 40   | 34.03 | 5.38 |          |       |       |
| Total Protein                   | BT   | 5.32  | 40   | 2.23 | 0.35 | -1.375 | 0.177 | NS    |

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RESULT
Statistically significant result was obtained in subjective parameters i.e., Prabhuta mutrata, Avila mutrata, Atishudha, Pipasaadhikya, Daurbalaya, Kar-pada daha. Statistically significant result also obtained in objective parameters i.e., blood sugar fasting and post prandial sugar level, eosinophil, Serum Bilirubin level and conjugated. Other objective parameters were non-significant.

DISCUSSION
Any research work without discussion about its nature, utility and importance is said to be incomplete. Any hypothesis/principle, if to be proved, must be discussed thoroughly from all angles. Discussion improves the knowledge and discussion with the Shastra, become the base of establishment of the concept. The present study entitled "Clinical study to evaluate the effect of Mustadi kwath in Madhumeha" was done on 40 patients.

Conceptual
Premeha is Kapha pradhan tridoshaja vyadi. Prameha is considered most troublesome “Anushangi Vyadi” in Ayurveda and has been included in Astha Mahagadas. Ayurvedic Acharyas considered genetics and acquired factors responsible for manifestation of Prameha. Two types of pathogenesis have been described in the Ayurvedic classics one is Aavarajaneya and second is Dhatu kshayajanya. Both of these cause Vata-prakopa but different mechanism.

In Aavarajaneya Madhumeha due to excessive indulgence of Guru, Snigdha, Amla, Lavana Ahara, Kapha and Pitta get vitiated. Vitiated Kapha and Pitta block the nature pathway of Vata. Getting hindrances in free flow, Vata get intensification. Thus aggravated Vata vitiates the Dushyas like Kapha, Meda, Mamsa and brings Oja to the urinary bladder and along with other Dushya excrete Oja through urine.

In case of Dhatu kshayajanya Madhumeha, Vata prakopakaahara –Vihara leads to aggravation and vitiation of Vata. Therefore, in this type Vata becomes more harmful than the previous type. This aggravated Vata disturbs the normal metabolism of body and cause Kshaya of all vital Dhatu. In both these types Aparaoja is excreted through urine.

In pathogenesis of Prameha Agnimandya particularly Dhatvagnmandya plays important role.

|                | AT   | 40 | 1.98 | -0.260 |
|----------------|------|----|------|--------|
| Albumin        | BT   | 40 | 1.30 | 0.796  |
|                | AT   | 40 | 1.20 | NS     |
| Globulin       | BT   | 40 | 1.15 | 0.397  |
|                | AT   | 40 | 1.27 | NS     |

In Premeha, especially Medo dhavagnimandya is observed. Derangement of Agni leads to Ama production at various levels. As a result, the process of Dhatuposhana and Dhatu-uptatti is hampered.

Diabetes mellitus is a clinical syndrome characterized by hyperglyceamia due to absolute or relative deficiency of insulin. Lack of insulin, whether absolute or relative, affects the metabolism of carbohydrate, fat, water and electrolyte. Two types of diabetes mellitus is observed in the people i.e., Type 1 and Type 2. In this Type 1, the process of beta – cell destruction occurs that may ultimately leads to diabetes mellitus. In this type insulin is required for survival to prevent the development of ketoacidosis, coma and death. Onset of symptoms is generally abrupt with polyuria, polydipsia and polyphagia. The Type 2 is characterized by disorder of insulin action and insulin secretion, either of which may be predominant feature. Patients of this type are generally obese and have mild onset of disease.

In the general survey of the patients the observation is as follow

In the current study, i.e., 32.5% of patients were aged 41-50 years. The incidence of type 2 D.M. may be indicated. It is more in the higher age group. Less physical activity and increased age could be the cause of this finding, while 25% or patients were of 51-60 and 61-70 age. 65% of patients were male and 35% of patients were female. The incidence of DM in men and women is comparable in most age ranges. Modern studies indicate that males and female suffer similarly from the disease, but males are most vulnerable than females to the effects of indolence and obesity and regional fat deposition.

In this study maximum number of patients i.e., 42.5% patients were desk worker, followed by 35% were housewives. In this observation of occupation we found maximum patients belongs to desk worker, housewives, both are related to physical inactivity thereby leading a sedentary lifestyle which leads to a less energy expenditure than uptake. The present study reveals that vegetarian dietary habits were found more (70%) than mixed (30%). This data is in consistence with population characteristics of Haridwar.

Current study reveals that the frequency of patients in weight group of 71-80kg was the highest.
47.5% followed by 30% of patients from 61-70 weight groups. This means most of the patients do not have physical activity and follow sedentary lifestyle.

**Effect of Therapy**

- Statistically significant result was found in subjective parameters like Prabhut Mutrata Aavila- Mutrata, Atikshuda, Pipasaadhikiya, Daurbalya, Kara-pada daha as, P-value for all parameters are less than 0.05.
- Statistically significant result was found in objective parameters like blood sugar fasting, postprandial blood sugar and HBALC as p-value for the parameters are less than 0.05.

   In the present study, complete relief in 27.5%, marked improvement in 50%, moderate improvement in 22.5% was found.

**Probable mode of action of Mustadi Kwath**

The Mustadi Kwath is Tridosha Shamaka especially Kapha- Vata Shamaka and also its contents have Laghu, Ruksha, Tikshna properties due to which it depletes the vitiated Kapha and Vata doshas which is dominant in the pathogenesis of Madhumeha.

**CONCLUSION**

Madhumeha is Kapha-vata pradhan vyadi which has symptoms similar to diabetes mellitus. Mustadi kwath had a significant result in Madhumeha. No adverse drug effects were observed at the end of trial, hence it is concluded that Madhumeha is effectively treated by Ayurvedic medicine.

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