



CLINICAL EVALUATION OF PHALATRIKADI KWATHA IN THE MANAGEMENT OF MADHUMEHA W.S.R. TO DIABETES MELLITUS

Dr. Monika Gupta*

Associate Prof., Deptt. of Kaya Chikitsa, JIAR, Jammu, India.

*Corresponding Author: Dr. Monika Gupta

Associate Prof., Deptt. of Kaya Chikitsa, JIAR, Jammu, India.

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ABSTRACT

Diabetes Mellitus is one of the most common non-communicable diseases globally. It emerged as a public health problem in India. Diabetes mellitus is a chronic metabolic disorder due to either insulin deficiency or due to peripheral tissue resistance to the action of insulin. In *Ayurveda*, this condition can be explained as *Madhumeha*. It is one of the types of *Prameha* where the patient passes honey like sweet urine (Raised level of sugar in urine & Hyperglycaemia). The main causative factor is said to be sedentary lifestyle, excessive intake of sweet, non-vegetarian, dairy product, jaggery (cane sugar preparations) and heavy & excess meals. In the present study we planned to get effective and safe treatment for "*Madhumeha*" with the help of clinical principles of *Ayurveda*. In the present study, 30 patients having *Madhumeha* were selected from O.P.D. & I.P.D. of Jammu Institute of *Ayurveda* & Research College and Hospital, Jammu. These patients were subjected to the following therapeutic Yoga namely *Phalatrikadi Kwatha*. Then assessment of therapy on signs and symptoms was done by adopting suitable scoring methods and repeating laboratory investigations and critically analyzed. The results thus obtained finally were subjected for statistical analysis for the therapy. The end results thus obtained were interpreted and graded as complete remission, marked improvement, moderate improvement and mild improvement and presented in details.

KEYWORDS: *Madhumeha, Phalatrikadi Kwatha, Ayurveda.*

INTRODUCTION

Diabetes mellitus is a metabolic disorder of multiple etiology, characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both. *Ayurvedic* remedies for *Madhumeha* (Diabetes mellitus) are the oldest among all the available therapies, which includes in the *Prameha* category. *Prameha* are a list of urinary disorders, especially characterized by profuse urination with several abnormal qualities due to imbalance of *Doshas*. In *Madhumeha* the urine becomes (sweet and smells) like honey. It is of two distinct types, one due to the aggravation of *Vata* on account of the *Dhatukshya* and the other due to *Kapha-meda Avarana* (Blockage of channel along with *Vata Prakopa*. When there is condition of *Avarana* (blockage of the channels/activity) there are the additional symptoms of the vitiation of the particular *Dosha* without any other apparent cause. Sometimes the symptoms are mild and suddenly they appear in severe form which is difficult to cure.

Etiology

Enjoying sedentary habits and the pleasure of sleep excessively, too much use of yoghurt and its preparation, meat juice of domestic, aquatic and swampy animals, milk and its preparation, newly harvested cereals, new/fresh wines, preparations of jaggery (cane sugar preparations) and all other *Kapha*-aggravating factors are the causes of the diabetes syndrome.

Pathogenesis (*Samprapti*)

Samprapti of *Madhumeha* is best described by *Acharya Vagbhatta*. He said *Madhumeha* can originate in two ways -

1. By the aggravation of *Vata* caused by *Dhatukshaya*.
2. By the obstruction of *Vata* caused by *Doshas* covering it.

Madhumeha which is caused by *Dhatukshaya* manifests as thin and asthenic individual due to loss of *Oja*. All this is *Ojakshaya* meaning an imbalance in *Ojus*. In *Margavaranjanya Madhumeha* the vitiated *Kapha* and *Meda* obstruct the passage of *Vata*. The obstructed *Vata* is vitiated again and carries *Ojus* to *Basti* thus manifests *Madhumeha*.

As per *Ayurveda* according to the potency of particular feature of etiology, *Dosha* (innate pathogenic factors) and *Dushyas* (substratum of pathology), response occurs in the form of non-manifestation or otherwise of the disorders. When these three factors do not combine together or if combined after a long time or in weakened state, disorder will not be there, or it will manifest lately, or in a mild form or without all the said symptoms. On the contrary, the result will be contrary. Thus is said the cause of response in the form of non-manifestation or otherwise of all disorders.

Epidemiological figures indicative of prevalence of disease worldwide are growing day by day and major share of India is quite alarming. According to data presented by WHO, more than 220 million people worldwide suffer from Diabetes. Although prevalence of both Type-1 & Type-2 Diabetes is increasing worldwide, the prevalence of Type-2 Diabetes is spreading more rapidly in developing countries because of increasing obesity, reduced activity levels & western style diet. In 2010, 45.2 million people in India were diabetic. By the end of 2016, this number will increase to 50.6 million. This is likely to be 71.4 million in 2030 which will be 115th of the total Diabetic population at that time. India has long passed the stage of epidemic & the number has given the country the dubious distinction of DIABETES CAPITAL OF THE WORLD.

Global access of Diabetes is increasing. Various Oral hypoglycaemic agents, Insulin formulations, life style modification plans consisting dietary management and exercise, are some of the important efforts towards the management of Diabetes. In spite of these, world is seeking for a safer and effective remedy. Increased side effects, lack of effective treatment for complications, high cost of new drugs and resistance to the drugs are some reasons for renewed public interest in *Ayurvedic* medicines. So, now it's a duty of an *Ayurvedist* to try to understand the disease and complications according to *Ayurveda* and to establish our time tested drugs as a prime therapy. Taking into account the hazardous nature of Diabetes and to establish efficacy of *Ayurvedic* compounds, present study entitled – “**Clinical evaluation of Phalatrikadi Kwatha in the management of Madhumeha w.s.r. to Diabetes mellitus**” was undertaken. The ingredients of this formulation mainly act on hyperglycaemia, gastritis, dyspepsia, indigestion, *Amlapitta*, etc.

MATERIALS AND METHOD

Selection of patients

For the present study, 30 patients with classical signs and symptoms of *Madhumeha* and patients who had blood glucose level more than normal limits were selected from OPD and I.P.D of Jammu Institute of *Ayurveda* and Research, Hospital.

Criteria for Diagnosis

• Inclusion Criteria

1. Patients were diagnosed on the basis of classical signs and symptoms of disease *Madhumeha* as per *Ayurvedic* texts.
2. After diagnosis diabetes specific biochemical investigations were carried out. Patients with F.B.S. level more than 126mg/dl and P.P.B.S. level more than 200mg/dl were selected for study.
3. A detail Performa was filled consisting Signs and Symptoms, Complete history of disease, Family history, *Dashavidha Pariksha* and *Ashtavidha Pariksha* was filled for every patient in favour to support the diagnosis of disease.
4. In addition to this, following laboratory investigations were carried out Urine-Routine and Microscopic. Blood - Hb%, TLC, DLC, ESR.

• Exclusion Criteria

1. Patients with Type-1 DM.
2. Patients with Type-2 DM who were insulin dependent.
3. Patients above age of 65 yrs.
4. Patients with severe diabetic complications like cardiovascular diseases, nephropathy, and retinopathy.
5. Diabetes due to endocrinopathies e.g. Pheochromocytoma, Acromegaly, Cushing's syndrome, Hyperthyroidism etc.
6. Pregnancy i.e. gestational Diabetes mellitus.

• Therapeutic regimen

Patients were randomly selected. All patients were given *Phalatrikadi Kwatha*. In those patients who were taking some oral hypoglycaemic agents, their blood sugar at that time was considered as a basal level and the patients were advised to take hypoglycaemic drug in the same dose. Effect of study drug was observed in relation to the basal records of symptoms and sugar levels.

• Diet and Exercise

Patients were advised to take diet which is in dictated for *Madhumeha*. Patients were encouraged for regular, suitable exercise and advised to avoid '*Apathya*' viharas.

• Criteria for Assessment

Effect of the treatment was assessed by assessing - Signs and symptoms before and after treatment. FBS, PPBS levels before and after treatment.

1) Prabhuta Mutrata (Polyuria)

| Grade | Frequency |
|-------|-----------|
| 0 | 3-5 |
| 1 | 6-9 |
| 2 | 10-12 |
| 3 | >12 |

2) *Avil Mutrata*

| Grade | Turbidity |
|-------|---|
| 0 | Clear urine |
| 1 | Slightly turbid |
| 2 | Turbidity clearly presents but news print can be read |
| 3 | News print cannot be read (more turbid) |

3) *Trishnadhikya (Polydipsia)*

| Grade | Frequency |
|-------|---|
| 0 | Normal |
| 1 | Mildly increased but tolerated |
| 2 | Moderately increased but tolerated |
| 3 | Severely increased but can't be tolerated |

4) *Kshudhadhikya (Polyphagia)*

| Grade | Frequency |
|-------|---|
| 0 | Normal |
| 1 | Mildly increased but tolerated |
| 2 | Moderately increased but tolerated |
| 3 | Severely increased but can't be tolerated |

5) *Kara-Pada-Tala-Daha (Burning sensation in hand & feet).*

| Grade | Daha |
|-------|--|
| 0 | No Daha |
| 1 | Occasionally noticed |
| 2 | Very often & regular activities not hampered |
| 3 | Whole day & regular activities are hampered |

6) *Daurbalya (General debility).*

| Grade | Daurbalya |
|-------|--|
| 0 | Can do routine work & exercise |
| 1 | Can do moderate exercise, with hesitancy |
| 2 | Can do mild exercise only, with difficulty |
| 3 | Can't do mild exercise either |

Biochemical Parameters

Blood Sugar Level: Blood sugar level [BSL] - FBS: 125mg/dl and PPBS: 200mg/dl were considered as base line. Improvement in blood sugar level of each patient was calculated by below mentioned formula.

$$\text{Improvement in FBS (\%)} = \frac{\text{Total BT} - \text{Total AT}}{\text{Total BT} - 125} \times 100$$

$$\text{Improvement in PPBS (\%)} = \frac{\text{Total BT} - \text{Total AT}}{\text{Total BT} - 200} \times 100$$

Results obtained from individual patient were categorized according to following gradation pattern

| Grade | Assessment | Criteria |
|-------|----------------------|---------------------------------------|
| 0 | No improvement | Improvement in BSL <25% or no change |
| 1 | Mild improvement | BSL25% (upto 50%) |
| 2 | Moderate improvement | BSL50% (upto 75%) |
| 3 | Marked improvement | Improvement in BSL75% |
| 4 | Control | Blood sugar level within normal range |

RESULTS AND DISCUSSION

Efficacy of Treatment

Signs and Symptoms of *Madhumeha*Table 1: Effect on *Prabhuta Mutrata*.

| | Mean Score | | % Relief | S.D. (±) | S.E. (±) | t | p |
|--------|------------|------|----------|----------|----------|-----|--------|
| | B.T. | A.T. | | | | | |
| N = 26 | 2.42 | 0.5 | 79.33 | 1.05 | 0.19 | 9.7 | <0.001 |

The table 1 shows that mean initial score for *Prabhuta Mutrata* was 2.42, which reduced to 0.5, showing 79.33% improvement. Statistical analysis shows that the improvement was highly significant at $P < 0.001$.

Table 2: Effect on *Avila Mutrata*.

| | Mean Score | | % Relief | S.D. (±) | S.E. (±) | t | p |
|-------|------------|------|----------|----------|----------|---|---|
| | B.T. | A.T. | | | | | |
| N = 4 | 0.21 | 0.21 | 0 | 0 | 0 | - | - |

Effect of therapy on *Avila Mutrata* shows no improvement with unchanged mean (0.21).

Table 3: Effect on *Kshudhadhikya*.

| | Mean Score | | % Relief | S.D. (±) | S.E. (±) | t | p |
|--------|------------|------|----------|----------|----------|------|--------|
| | B.T. | A.T. | | | | | |
| N = 20 | 1.71 | 0.67 | 60.23 | 0.88 | 0.16 | 6.22 | <0.001 |

The mean score for *Kshudhadhikya* was 1.71 in the beginning, which reduced to 0.67 at the end of treatment, showing 60.23% improvement. Statistical analysis shows that the improvement was highly significant giving 't' value 6.22.

Table 4: Effect on *Trishnadhikya*.

| | Mean Score | | % Relief | S.D. (±) | S.E. (±) | t | p |
|--------|------------|------|----------|----------|----------|------|--------|
| | B.T. | A.T. | | | | | |
| N = 26 | 2.17 | 1.07 | 50.69 | 0.83 | 0.15 | 7.04 | <0.001 |

Effect on *Trishnadhikya* reveals that B.T. mean score was 2.17 which reduced to 1.07 with 50.69% relief, giving 't' value of 7.04 which is highly significant at 'p' <0.001.

Table 5: Effect on *Kara-Pada-Tala-Daha*.

| | Mean Score | | % Relief | S.D. (±) | S.E. (±) | t | p |
|--------|------------|------|----------|----------|----------|------|-------|
| | B.T. | A.T. | | | | | |
| N = 14 | 0.71 | 0.54 | 33.7 | 0.47 | 0.08 | 1.98 | >0.05 |

Effect on *Kara-Pada-Tala-Daha* by this therapy was 33.7%. The initial mean score was 0.71 which decreased to 0.54 after treatment giving 't' value of 1.98 which is insignificant at $P > 0.05$.

Table 6: Effect on *Daurbalya*.

| | Mean Score | | % Relief | S.D. (±) | S.E. (±) | t | p |
|--------|------------|------|----------|----------|----------|------|-------|
| | B.T. | A.T. | | | | | |
| N = 14 | 0.71 | 0.54 | 33.7 | 0.47 | 0.08 | 1.98 | >0.05 |

Mean scores for *Daurbalya* before and after treatment were 2.1 and 0.64 respectively. It showed 69.5% relief with 't' value 13.14 which is highly significant at $P < 0.001$.

Blood sugar levels

Table 7: Effect on F.B.S.

| | Mean Score | % Relief | S.D. (±) | S.E. (±) | t | p |
|--------|------------|----------|----------|----------|------|--------|
| N = 28 | 20.67 | 54.15 | 9.6 | 1.8 | 11.2 | <0.001 |

Mean score of improvement in F.B.S. calculated by formula, was 20.67 which shows 54.15% relief giving 't' value of 11.2 which is highly significant ($P < 0.001$).

Table 8: Effect on P.P.B.S.

| | Mean Score | % Relief | S.D. (±) | S.E. (±) | t | p |
|--------|------------|----------|----------|----------|------|--------|
| N = 28 | 14.92 | 37.2 | 8.5 | 1.6 | 9.28 | <0.001 |

Mean score of improvement in P.P.B.S., calculated by formula, was 14.92 which shows 37.2% relief giving 't' value of 9.28 which is highly significant ($P < 0.001$).

Overall Effect of Therapy**Table 9: Improvement in Signs and Symptoms.**

| Results | Patients | % |
|----------------------|----------|-------|
| Controlled | 1 | 3.57 |
| Marked improvement | 3 | 10.7 |
| Moderate improvement | 13 | 46.4 |
| Improved | 11 | 39.28 |
| Unchanged | 0 | 0.00 |

1 patient was (3.57%) assessed as controlled and 3 patients (10.7%) as markedly improved. Moderate improvement was seen in 13 patients (46.4%), whereas,

mild improvement was observed in 11 patients (39.28%). All patients responded to treatment to some extent and no patient assessed as unchanged.

Table 10: Improvement in Blood Sugar Level.

| Results | F.B.S. | | P.P.B.S. | |
|----------------------|----------|-------|----------|------|
| | Patients | % | Patients | % |
| Controlled | 7 | 25 | 3 | 10.7 |
| Marked improvement | 6 | 21.4 | 3 | 10.7 |
| Moderate improvement | 8 | 28.6 | 7 | 25.0 |
| Improved | 1 | 3.6 | 8 | 28.5 |
| Unchanged | 5 | 17.85 | 7 | 25.0 |

CONCLUSION

Secrets of healthy life are minutely described in *Ayurveda*. *Dinacharya*, *Ritucharya*, *Annapana Vidhi* are some of these secrets. Though it is true that modernization of life style is responsible for the increasing prevalence of *Madhumeha* in community. *Madhumeha* is known to *Acharyas* since long and they were the masters as far as the diagnosis and treatment of *Madhumeha* is concerned. Diabetes mellitus, a metabolic disease described by Allopathic medical science, can be simulated with *Madhumeha*.

Data presented by WHO is quite indicative of increasing prevalence of DM (*Madhumeha*) in the community. This is an effort to find out an effective remedy for *Madhumeha* (DM), present study entitled. "**Clinical evaluation of *Phalatrikadi Kwatha* in the management of *Madhumeha* w.s.r. to Diabetes mellitus**" was undertaken.

Study was persuaded in the direction of following Aims and Objectives

1. To study etiopathogenesis and symptomatology of *Madhumeha* and Diabetes mellitus simultaneously.
2. To assess the efficacy of *Phalatrikadi Kwatha* on signs and symptoms of *Madhumeha* (DM).
3. To assess the role of *Phalatrikadi Kwatha* on diabetes specific biochemical.

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