A COMPARATIVE STUDY ON KATAK KHADIRADI KASHYAYAM AND NIRURYADI GULIKA IN THE MANAGEMENT OF MADHUMEHA W.S.R. TO HYPERGLYCEMIA

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ABSTRACT

The study was conducted on 40 clinically diagnosed patients of hyperglycemia with an objective of clinical evaluation of the efficacy of Katak Khadiradi Kashyayam and Niruryadi Gulika in the management of Madhumeha (Hyperglycemia). These patients were randomly divided into three groups of 10 patients each. Out of that 30 patients has been completed clinical trial and 10 patients was drop out.

The study confirms that Katak Khadiradi Kashyayam and Niruryadi Gulika is effective in management of Madhumeha and definitely reduces the symptoms of illness that includes Prabhuta mutrata (Polyuria), Klama (early fatigue), Alasya (Lassitude), Vibandh (Constipation) (In Group 3) including Aty sweeda (Sweating), Mukha shosha (Dryness of mouth) (In Group 1).

The chosen drug is effective (laboratory parameters) in reducing Post Prandial Blood Sugar and, Post Prandial Urine Sugar (In group 2 and 3) (highly significant in group 3 and significant in group 2), only PPBS in Group 1 (significant result). No adverse effects were noted in any of the patients during the trial period.

Keywords: Madhumeha, Hyperglycemia, Katak Khadiradi Kashyayam, Niruryadi Gulika

INTRODUCTION

All those patients who pass urine which is sweet & resembles like honey and the body also becomes sweet are said to be suffering from Madhumeha. In Brihatrayi detailed description of aetiological factors of Prameha are available and etiology described there is very near to current aetiological factors for DM (Diabetes mellitus). According to the International Diabetes Federation, the number of diabetic patients in India more than doubled from 19 million in 1995 to 40.9 million in 2007. It is projected to increase to 69.9 million by 2025. Currently, up to 11% of India’s urban population and 3% of rural population above the age of 15 have diabetes. Calling India the diabetes capital of the world, the international journal of diabetes in developing countries says that there is alarming rise in prevalence of diabetes, which has gone beyond epidemic form to a pandemic one.

According to pathogenesis and clinical manifestation, Diabetes mellitus can be easily correlated with madhumeha. Madumeaha is being described under the subtype of vataja prameha. It has been broadly elaborated in main ancient Ayurveda texts like Brihatraye and Laghutraye. Considering the seriousness of the condition and its prognosis, it is being too referred to Mahagada or Maharoga.

A Diabetes Mellitus, the most common endocrine disorder and a clinical syndrome characterized by hyperglycaemia due to relative or absolute deficiency of insulin resulting in long standing metabolic derangements associated with pathophysiological changes in multiple organ system of eyes, kidneys, nerves and vascular system being characteristically susceptible.

The W.H.O. estimates that mortality from diabetes and heart disease cost India about $120 billion every year and is expected to
increase to $335 billion in the next ten years. These estimates are based on lost productivity, resulting primarily from premature death.

Diabetes mellitus is a growing health hazard in developing countries. As a psychosomatic disease and due to most dangerous complications, diabetes mellitus has grabbed the attention of health community all over the world. Globally, diabetes affects 246 million people, which is about 6% in the total adult population. It is the 4th leading cause of death by disease and every 10 sec a person dies from diabetes related causes in the world. The Top ten countries, in numbers of sufferers, are India, China, USA, Russian Federation, Brazil, Germany, Pakistan, Japan, Indonesia and Mexico.

**AIMS AND OBJECTIVES**
The present research trial has been undertaken with the following main objectives-

- Conceptual and clinical studies on *Mudhumeha* W.S.R. to Hyperglycemia and its management with time tested *Ayurvedic* principles.
- To evaluate Antihyperglycemic effects of the *Katak Khadiradi Kashyayam* (Sahasra Yogam, CCRAS publication, *pratham prakaran – kashyaya yog* 71, page no.16 ) and *Niruryadi Gulika* (Sahasra Yogam, CCRAS publication, *duvitiya prakaran – gutika yoga* 69, page no.142 ) in a series of patients suffering from *Madhumeha* on various scientific parameters.
- To compare the efficacy of Antihyperglycemic effects of the *Katak Khadiradi Kashyayam* and *Niruryadi Gulika*

**MATERIALS AND METHODS**
1. Selection of cases

   The study recruited a population of 40 clinically diagnosed patients of *Madhumeha* (hyperglycemic) selected from O.P.D / I.P.D. unit of P.G. Department of *Kayachikitsa*, National Institute of Ayurveda, Jaipur and Seth Surajmal Bombewala Hospital, Kishanpole Bazar, Jaipur. Out of which 30 patients has been completed clinical trial and 10 patients was drop out during the trial period. A regular record of the assessment of all patients was maintained according to proforma prepared for the purpose. Following inclusion and exclusion criteria’s were used for registration of the patients for present clinical trial.

   (a) Inclusion criteria

   - Patient with clinical history of DM.
   - Patient having hyperglycaemia confirmed by laboratory investigation.
   - Presence of Cardinal symptoms of *Madhumeha* as described in *Ayurveda* texts.

   (b) Exclusion criteria

   - Patient having Type 1 DM.
   - Age below 20 and above 70 years.
   - Patient of Type II DM who were on insulin therapy.
   - Complication with DM.
   - Patient having any serious illness.
   - Patient having a FBS >250 AND PPBS >300.

2. Selection of drugs

   Taking the symptoms and the *Samprapti* of *Madhumeha* into consideration, a “*Katak Khadiradi Kashyayam* and *Niruryadi Gulika*” has been selected. The drug selected for the study a *Katak Khadiradi Kashyayam* were mainly having *Tikta, Katu, Kashaya rasa*, *Katu Vipaka, Laghu, Ruksha & Tikshna Guna pradhana aoshdhi*. All the selected drugs were having *Mutrasagrahaniya, Jatharagni vardhak, vayasthapana, chakshushya, rasayan, vrishya, grahi, lekhana, deepana, oja vardhana and pachana*. 
Method of preparation of Kashyayam:

Decoction (Kvātha or Kasāya) is the filtered liquid obtained by boiling coarse powder of drug(s) in proportion of 4, 8 or 16 [Mrudu Dravya - 4, Madhyama Dravya - 8 and Kathina Dravya - 16 respectively] times of water and reduced to one-fourth.

Therefore from above Contents of Katak Khadiradi Kashaya drugs is in madhyama form. For the preparation of decoction from no.1 to no.12 of drugs were taken in equal quantity and checked out for their identity, quantity and quality. The individual drugs were mixed in equal quantity and made into bharad form. After that two teaspoon (10 gm) of Yavakuta Churna (coarse powder) is taken for preparation of decoction in the 80 ml of water, a proper (mild) heat is given and when it reduces up to 20 ml filter through the muslin cloth, now decoction is ready to drink before meal (bid).The medicine Yavakuta Churna (coarse powder) was prepared in the pharmacy of N.I.A., Jaipur.

Method of administration: Orally in the form of decoction in a dosage of 20 ml twice in a day.

Duration of the trial: The clinical trial was continued for 30 days with each patient with a 15 days review.

Niruryadi gulika was purchased from pharmacy of Arya vaidya sala, Kotakkal.
Dose and Anupana: Dose of Niruryadi gulika was 2 tablets (each of 500 mg) in the afternoon before lunch and at night before the dinner with Luke warm water for 30 days.

3. Pre Treatment Observations
All the patients have been studied along with the registration by noting down their demographic profile including their age, sex, address, occupation, education, socio economic status, marital status, life style, addictions, dietary habits etc. After preliminary registration, patients were subjected to detailed case history taking, physical, general and systemic examinations. In history and examination importance was given to symptoms of Madhumeha. During this all other relevant information’s like Ashtavidha Pariksha and Dashvidha pariksha including assessment of Sharirika Prakriti and Manasika Prakriti (based on the features described in classical texts) etc. were noted.

4. Administration of Drug & Treatment Schedule
40 registered, clinically diagnosed and confirmed patients of Madhumeha (Hyperglycemic) were selected for the present clinical trial and randomly divided into following three groups out of that 30 patients has been completed clinical trial and 10 patients was drop out during the trial period.

GROUP- I: 10 patients of Madhumeha (Hyperglycemic) were administered Katak Khadiradi Kashyayam in a dose of 20 ml twice daily for a period of 30 days before meal.

GROUP- II: 10 patients of Madhumeha (Hyperglycemic) were administered Niruryadi Gulika in a dose of 2 tablet (each of 500 mg) with lukewarm water twice daily for a period of 30 days before meal.

GROUP- III: 10 patients of Madhumeha (Hyperglycemic) were administered Katak Khadiradi Kashyayam in a dose of 20 ml twice daily for a period of 30 days before meal and Niruryadi Gulika in a dose of 2 tablet (each of 500 mg) with lukewarm water twice daily for a period of 30 days before meal. All the patients were advised to undergo following laboratory investigations before starting the trial to rule out a hyperglycemia and other illness; if present then exclude them from the trial.

a) Blood Examinations
(i) F.B.S. (Fasting Blood Sugar)
(ii) P.P.B.S. (Post Prandial Blood Sugar)
(iii) C.B.C. and E.S.R.

b) Urine Examination
(i) Routine Examination
(ii) Microscopic examination.
(iii) F.U.S. (Fasting Urine Sugar)
(iv) P.P.U.S. (Post Prandial Urine Sugar).

Patients were followed up after 15 days and changes, improvements, deterioration and any other effects produced after the therapy were noted down.

5. Criteria for Assessment
After the completion of the treatment, the results were assessed by adopting the following criteria.

- Improvement in signs and symptoms of disease on the basis of symptoms score.
- Improvement in laboratory Investigation (i.e. reduce levels) on the basis of lab reports.
- Reduction in Objective assessment parameters.

For clinical evaluation the criteria can be divided in to two types:

1. Subjective Assessment
2. Objective Assessment

1. Subjective assessment

All symptoms taken for the assessment of clinical improvements were thoroughly examined and the severity of each symptom was rated before and after the trial for clinical assessment. For this purpose the following "Symptom Rating Scale" developed by Prof. K. Govardhan et.al was used.

A. Prabhoot Mootrata (Polyuria)
Frequency of Urine
3-6 times/day, rarely at night - 0
7-9 times /day, 0-2 times/night - 1
10-12 times /day, 2-4 times/night - 2
> 13 times /day, >4 times/night - 3

B. Swedadhikya (Excessive Sweating)
Normal Perspiration - 0
Mild after doing exertion - 1
Moderate after exertion - 2
Severe after exertion - 3
Perspiration without exertion - 4

C. Klama (Early fatigue)
No fatigue - 0
Mild after doing work - 1
Moderate after doing work - 2
Severe after doing work - 3
Feeling fatigue without doing work - 4

D. Aalasya (Lassitude)
Normally active - 0
Hesitate to start work but once started completed - 1

Clinical Improvement

Table 3: Showing the overall comparative improvement in clinical feature of Madhumeha in three treated groups

<table>
<thead>
<tr>
<th>S. No</th>
<th>Symptoms</th>
<th>Group I</th>
<th></th>
<th>Group II</th>
<th></th>
<th>Group III</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>p</td>
<td>Result</td>
<td>%</td>
<td>p</td>
<td>Result</td>
<td>%</td>
</tr>
<tr>
<td>1.</td>
<td>Prabhuta mutrata</td>
<td>33.33</td>
<td>&lt; 0.05</td>
<td>S.</td>
<td>50</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
</tr>
<tr>
<td>2.</td>
<td>Avilmutrata</td>
<td>21.1</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
<td>21.1</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
</tr>
<tr>
<td>3.</td>
<td>Pipasadhikya</td>
<td>22.2</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
<td>22.2</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
</tr>
<tr>
<td>4.</td>
<td>Kshudhadhikya</td>
<td>27.3</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
<td>0</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
</tr>
<tr>
<td>5.</td>
<td>Ati sweda</td>
<td>42.9</td>
<td>&lt; 0.01</td>
<td>S.</td>
<td>33.3</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
</tr>
<tr>
<td>6.</td>
<td>Hastapada &amp; Sandhi shoola</td>
<td>37.5</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
<td>30</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
</tr>
<tr>
<td>7.</td>
<td>Klama</td>
<td>25</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
<td>46.2</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
</tr>
<tr>
<td>8.</td>
<td>Mukha shosha</td>
<td>38.5</td>
<td>&lt; 0.01</td>
<td>S.</td>
<td>44.4</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
</tr>
</tbody>
</table>

2. Objective assessment

(a) Assessment of Body Mass Index (B.M.I). (Weight in kg/height in meter²)
18.5-24.9 - 0
25 – 29.9 - 1
30 - 34.9 - 2
35 - 39.9 - 3
> 40 - 4

OBSERVATIONS AND RESULTS

Subjective improvement

After the completion of therapeutic trial there was marked improvement in the Prabhuta mutrata (Polyuria), Klama (early fatigue), Alasya (Lassitude), Vibandh (Constipation) (In Group 3) including Ati sweda (Sweating), Mukha shosha (Dryness of mouth) (In Group 1).

9. Alasya 40 <0.05 S. 44.4 > 0.05 N.S. 53.3 <0.05 S.
10. Vibandh 50 <0.05 S. 28.6 > 0.05 N.S. 87.5 <0.05 S.
11. Karapada tala daha 11.1 > 0.05 N.S. 16.7 > 0.05 N.S. 28.6 > 0.05 N.S.
12. Mukhamadhurya 40 > 0.05 N.S. 50 > 0.05 N.S. 40 > 0.05 N.S.
13. Jananang Kandu - - - 0 > 0.05 N.S. 100 > 0.05 N.S.
14. Kapa pada tala supi - - - 42.9 > 0.05 N.S. 0 > 0.05 N.S.

Objective parameters
- Study on changes in blood sugar have revealed that there was significant reduction (Group I and II) and highly significant (in Group III) in the level of post Prandial blood sugar in the all the patients of three groups but the percentage of reduction was maximum in patients of Group-III, where Katak Khadiradi Kashyayam was administered with Niruryadi Gulika, also significant reduction in fasting blood sugar in patient of Group-III. (Table No. IV)
- Significant reduction in the level of post prandial urine sugar in Group-II and highly significant reduction was observed in patients of Group-III. (Table No. IV)

Table 4: Showing the overall comparative improvement in lab parameters of Madhumeha in three treated groups

<table>
<thead>
<tr>
<th>S. No</th>
<th>Lab Investigation</th>
<th>Group I</th>
<th>Group II</th>
<th>Group III</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>P</td>
<td>Result</td>
<td>%</td>
</tr>
<tr>
<td>1</td>
<td>Fasting Blood Sugar</td>
<td>6.85</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
</tr>
<tr>
<td>2</td>
<td>Post Prandial Blood Sugar</td>
<td>16.97</td>
<td>&lt;0.05 S.</td>
<td>13.86</td>
</tr>
<tr>
<td>3</td>
<td>Fasting Urine Sugar</td>
<td>20</td>
<td>&gt; 0.05 N.S.</td>
<td>12.5</td>
</tr>
<tr>
<td>4</td>
<td>Post Prandial Urine Sugar</td>
<td>17.9</td>
<td>&gt; 0.05 N.S.</td>
<td>42.1</td>
</tr>
<tr>
<td>5</td>
<td>Hb g%</td>
<td>3.27</td>
<td>&gt; 0.05 N.S.</td>
<td>1.5</td>
</tr>
<tr>
<td>6</td>
<td>ESR</td>
<td>20.4</td>
<td>&gt; 0.05 N.S.</td>
<td>40</td>
</tr>
<tr>
<td>7</td>
<td>TLC</td>
<td>7.29</td>
<td>&gt; 0.05 N.S.</td>
<td>6</td>
</tr>
</tbody>
</table>

Table 5: Showing the overall comparative physiological improvement in three treated groups

<table>
<thead>
<tr>
<th>S. No</th>
<th>Physiological parameters</th>
<th>Group I</th>
<th>Group II</th>
<th>Group III</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>p</td>
<td>Result</td>
<td>%</td>
</tr>
<tr>
<td>1</td>
<td>Body Wt. (Kg)</td>
<td>0.5</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
</tr>
<tr>
<td>2</td>
<td>BMI (Body mass index)</td>
<td>0.63</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
</tr>
<tr>
<td>3</td>
<td>Systolic blood pressure</td>
<td>0.48</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
</tr>
<tr>
<td>4</td>
<td>Diastolic Blood Pressure</td>
<td>1.3</td>
<td>&gt; 0.05</td>
<td>N.S.</td>
</tr>
</tbody>
</table>

HS= Highly Significant, S= Significant, NS= Not Significant

Probable mode of action of Katak Khadiradi Kashyayam

Jatharagni mandya is present in Madhumeha and Katu, Tikta rasa present in kashyayam it may act in vardhana of agni. Kashaya rasa is present up to 83.33%, which may produce Mutrasamgrahniya prabhava. Tikta, Kashaya rasa present in this formulation produces Shoshana effect. Hence the Prabhoota mutrata in Prameha tend to regress.

When predominant Gunas is present in research drug are assessed it becomes evident that most of the drugs possess Laghu, Ruksha Guna (i.e. 100% and 75%). Ruksha guna helps in alleviation of Bahudrava shlesha and Abaddha meda, the annexation of two being initial triggering event in samprapti of disease. Obstruction of Vata by Kapha and medas as Kapha here aarambhak dosha and Vata is preraka dosha. Laghu and Ruksha guna by virtue of their kaphaghana and medoghana prabhava help in reducing tissue weight. Now it can be suspected that kashaya rasa, Laghu, Ruksha guna like properties can further aggravate vitiated Vata dosha in Madhumeha. In this context it is proposed that here it is obstructed Vata (primarily by Kapha & Medas) which is causing trouble; Vata here may not be increased quantity wise in body, only obstruction is there in
its natural passages which can be alleviated by Kaphahara, medohara drugs.

In the compound majority of drugs are found to have Ushna Virya. In 1979 at BHU, Varanasi has proved that substance having Ushna Virya is accountable for breakdown of fat at mitochondrial level. Meda is invariably involved in pathogenesis of disease. According to Ayurveda principles Ushna virya helps in alleviation of Kapha and Vata.

As far as Vipaka is concerned katu vipaka enhances jatharagni, dhatvagni and normalize metabolic process. Sheeta virya and Madhura vipaka helps in replenishment of Ojus which become depleted with disease progression owing to continued exposure of body to vitiated Vata. The drugs in compound formulation also possess vayasthapana, chakshushya, rasayan, vrishya, grahi, lekhana, deepana and pachana properties.

It has been clear from above account that Katak Khadiradi Kashyayam can well disintegrated Samprapti of Madhumeha by acting at various levels i.e. alleviating dhatvagnimandya owing to presence of certain deepana pachana drugs in it like Bruhati, Mustak and Haridra also rukshata and laghuta present in drug will combat increased Kapha and meda which similitude in their properties. Aamalki and Haritaki are two drugs, which are known to exert rasayan prabhava too thereby causing oja vardhana, which is being depleted in body of Madhumeha owing to chronic exposure to Vata in body.

Probable mode of action of Niruryadi Gulika

In Niruryadi Gulika the maximum drug having a Kashaya, Tikta and Madhur Ras; Laghu, Rukshya and Guru guna; Sheeta Virya ; Madhur and Katu Vipaka.

According to Charak

Kinchidrasena kurute karma viryane chaparam |
Dravyam gunen paken prabhaven cha kinchan || Ch.Su. 26/71

According to above quotation, drug acts in the body in various ways. The Samprapti of Madhumeha is described earlier, for breakdown of that Samprapti the action of above ras, guna, virya and vipak are described as follows.

In the Niruryadi Gulika the Kashaya ras (64.70%) posses a properties like Sangrahi, Sthamban, Sharirikledasyopayokta due to that a polyuria is one of the main symptoms that can be manage, and due to the Sharirikledasyopayokta properties a abhaddha meda and kleda that can get soaked.

Tikta Ras (58.82%) having a properties like Srotomukhavishodhan, Ama pachaka, Murcha, Daha, Kandu, Kushatha, Trushna prashamana, Dipan, Pachana, Lekana, Sharira Kleda Soshana, Meda Soshana, Lasika Soshana, Swada Soshana, Mutra Soshana. From these properties it is very clear that in the complication of Madhumeha like Murcha, Daha, Kandu and Kushatha it plays a role. A polydypsia is one of the prime symptoms that can be subsiding by this ras (Trushna prashamana). The above described Kleda, Meda, etc. soshana properties of this ras helps for breakdown of Dosha –Dushaya Samurchana.

Madhura Ras having a properties like Bala-Varnakar, Marutagna, Trushana, Daha Prashaman, Prinan, Jivan, Santarpana, Brumhana, Sthryakara, Murcha Prashamana. According to these properties
it shows that it provide a strength to the Madhumehi patients because all dhatu kshaya is found in Madhumeha (Ojomeha) and also helps to nourished all dhatu(Saptadatu poshak).

Aamalki and Haritaki are two drugs, which are known to exert rasayan prabhava too thereby causing oja vardhana.

According to Guna, laghu (70.58%) is lekhana therefore it work on aavabadhya meda, kleda, and mamsa ; rukshya(52.94%) is soshana and stambhana properties it may be work on the polyuria. A Katu Vipaka also doing the same work like a mutra baddha. From above discussion it is hypotheses that, this Gulika work on the Prameha and Madhumeha like condition.

CONCLUSION
From present study following observations can be concluded: The disease Madhumeha is well documented in all perennial sources of Ayurvedic wisdom. Madhumeha has been discussed in Prameha roga as one of the Vataj Prameha. Literary evidence proves its modern correlate as Diabetes Mellitus. In this study it is found that Madhumeha mostly affects individuals in 5th, 6th and 7th decade of life with slight male preponderance. Prevalence is seen more in married. As every sort of Prameha (20 types) bear every possibility to terminate ultimately into Madhumeha if left untreated so general aetiopathological factors, pravapupa etc. can well be appreciated for Madhumeha too. The study confirms that Katak Khadiradi Kashyayam And Niruryadi Gulika is effective in management of Madhumeha and definitely reduces the symptoms of illness that includes Prabhuta mutrata(Polyuria), Klama (early fatigue), Alasya (Lassitude), Vibandh (Constipation) (In Group 3) , including Ati sweda (Sweating), Mukha shosha (Dryness of mouth) (In Group 1). The chosen drug was effective in reducing Post Prandial Blood Sugar and Post Prandial Urine Sugar (In group 2 and 3) (highly significant in group 3 and significant in group 2) and also shows a significant result in Group 1 P.P.B.S. All the patients tolerated medicines very well and no side effects were reported by any of the patients, suggesting that the drugs selected for current clinical trial are absolutely safe for internal use. After overall scrutiny, it can be concluded that the proposed Katak Khadiradi Kashyayam and Niruryadi Gulika in current research exhibits significant hypoglycaemic activity and can be given safely in patients of Madhumeha.

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