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# To Study the Efficacy of *Guduchi Kwath* with Oral Hypoglycemic Drugs in *Madhumeha* w.s.r. to Diabetic Mellitus

**[1] Vd. Bhoir Vijay , [2] Vd. V. E. Gogate , [3] Vd.Bhoir Vedika**

[1]M.D.(Kayachikitsa) Assi. Professor Bapuji ayur. College, Challkhere, Karnataka
[2] M.D.(Kayachikitsa) Asso. Professor Government Ayurved College,Nanded. Maharashtra
[3] M.S.(Shlyatantra) Assi. Professor D.Y.Patil School of Ayurveda Navi Mumbai, Maharashtra

**ABSTRACT:**

This paper reports about results of a prospective, randomized, control single blind trial to evaluate the efficacy of *Guduchi Patra Bharad* in *Kwath* along with oral hypoglycemic drugs in to *Madhumeh* with special reference Diabetes Mellitus with control of only hypoglycemic drug. Trial group having 30 patients of Madhumeha (DM) was treated with oral hypoglycemic drugs maximally two regimens [i.e. Metformin +Sulfonylurea] advice by allopathic expert with *Guduchi Kwath*. Control group with 30 patients of *Madhumeha* (DM) was treated with oral hypoglycemic drugs [i.e. Metformin +Sulfonylurea] advice by allopathic expert. 60 Patients were randomly selected and divided. Experimental group A was treated with *Guduchi kwatha* in continuation with previous oral hypoglycemic drugs (Metformin 500 mg + sulphonylurm group B was treated with oral hypoglycemic drugs only. Each group of patients were advised a standard diabetic diet. Prevalence of *Madhumeha* was found more in 40-60 years age groups, mostly in service persons and businessman's having family history of *madhumeha, kaphavata and kaphapitta prakruti*. It showed that BSL (F), BSL (PP), Urine (F), Urine (PP), *Prabhootmutrata, Aavil mutrata, Naktamutrata*, were significantly reduced in both experimental group A and control group B. Comparison of both treatments shows that treatment of experimental groups A were significantly effective than that of control group B in case of BSL (F), BSL (PP), Urine (F), Urine (PP), *Prabhootmutrata, Availamutrata, Naktamutrata.*

**Key Words**- *Madhumeh, Guduchi*, Hypoglycemic drugs, Diabetes Mellitus.

## INTRODUCTION

Diabetes mellitus is a metabolic disorder of carbohydrate, fat, & protein characterized by hyperglycemia with or without glycosuria. Diabetes mellitus is one of the leading causes of morbidity and mortality. Recent survey conducted by World Health Organization (W.H.O.) has revealed that the in 2015, an estimated 1.6 million deaths were directly caused by diabetes. Another 2.2 million deaths were attributable to high blood glucose in 2012. Almost half of all deaths attributable to high blood glucose occur before the age of 70 years. WHO projects that diabetes will be the seventh leading cause of death in 2030. The top three countries for number of persons with diabetes are India, China and United States of America. Out of total diabetic population 1/3rd belongs to India. So India has been declared as "Capital of diabetes".

Globally and Nationally the Diabetes Mellitus with its complications has become the most important contemporary and challenging health problem.

It is most often treated with diet and exercise, typically in conjunction with oral hypoglycemic drugs (OHD). Controlling the disease is paramount because there is no cure and the complications are so critical and

hazardous. Oral hypoglycemic agents and insulin used for the treatment of diabetes mellitus by the allopathic system of medicine have numerous side effects. Ayurveda because of its holistic approach not only aims to achieve strict glycemic control but also treat root cause of the disease..

*Guduchi* is one of the medicinal plant which is *Tikta, Katu, Kashaya rasatmak*, having *Madhur vipak, Ushna virya & Laghu, Snigdha ,Tridoshaghna Guna* which exactly opposite to pathophysiological factors of *Madhumeha*. As well as drug is easily available, cost effective and has no adverse effects noted so far. It was thought in mind to evaluate the role of *Guduchi patra kand bharad* in form of *Guduchi Kwath* with oral hypoglycemic drugs.

Because in Pakistan, research work on Alloxan Rabbits shows that extract of leaves (*patra)* of *Guduchi* has insulin like action and reduce BSL. Hence one such attempt has been made here by tabbing a jewel from the treasure of Ayurveda.

**AIM:** To Study the Efficacy of *Guduchi Kwath* with Oral Hypoglycemic Drugs in *Madhumeha* w.s.r. to Diabetic Mellitus.

**Objectives:**

- To Study Prameha Madhumeha chikitsa as per ancient Ayurvedic texts.
- To study effects of Guduchi Kwatha in Prameha-Madhumeha.

## MATERIAL AND METHODS

**SOURCE OF DATA:** A control single blind trial had taken up. The sample size was 60 in total. The Patients were collected from inpatient & outpatient department of *Kaychikitsa* Department of Government Ayurvedic hospital, Nanded by simple random sampling procedure, fulfilling the selection criteria.

**Drugs : Dose and Time of Administration**

Guduchi Kwatha -Guduchi (Patra & kand Bharad

Dose : 1 Pala i.e. 40 ml.Before meal. Time: Twice a day

**Preparation of *Guduchi (***Tinospora cardifolia) ***-kwatha*:**

- According to Sharandhar Samhita kwatha was prepared.
- 20 gm Bharad of Guduchi (Patra & kand Bharad) taken.
- Its 16th times i.e. 320 ml. water was added to it.
- Then the mixture was heated on low flame (mandagni) up to 40ml. will remain.
- Then it was filtered.

## STANDARDIZATION OF THE DRUG:

Standardization of the drug was done in Government Ayurveda Rasashala Nanded. Analytical reports are as follows –

**Analytical Reports**

| Sr. No. | Parameter | Result |
|---|---|---|
| 1 | Specific Gravity | 1.0084 |
| 2 | Relative Viscosity | 1.3093 Poise |
| 3 | Dynamic Viscosity | 1.2782 Poise |
| 4 | Kinematic Viscosity | 1.2675 Stokes |
| 5 | % Acidity for 100ml of Guduchi Kwath | 133ml of 0.1N NaOH |
| 6 | Refractive index | 1.3349 |

**Oral hypoglycemic drugs :**

Clinical Trial: Study Period: 2009 to 2012 Study, Place: Government Ayurveda College and Hospital, Nanded. This was prospective, randomized, control single blind clinical trial. They were randomly divided into two groups for further study.

Institutional ethics committee approval and regulatory compliance: Before the initiation of the study, the study protocol and related documents were reviewed and approved by Institutional Ethics Committee at GAC, Nanded. The study was conducted in accordance with Schedule Y of Drugs and Cosmetics act, India. Ethical Clearance for the study was taken from Institutional Ethical Committee GACN/VV/IEC1995-2001/2010Date-19/03/10. PG/2014-15/20-9-2015.

**Methodology :**

Thorough history and the complaints of the patients were taken in their chronological order. Each & every patient was carefully examined clinically for general and systemic examination.

Full explanation about the trial was given to each patient & informed written consent of each patient was taken before the commencement of treatment, after that total 60 patients were selected for present clinical trial on the basis of clinical diagnosis.

Total 60 patients of Madhumeha were randomly selected & equally divided into two groups, of which one group is again sub-divided in to two as below

**1]Experimental Group:** In this group, 30 Patients of Madhumeha (DM) taking oral hypoglycemic drugs maximally two regimens [i.e. Metformin +Sulfonylurea] advice by allopathic expert with Guduchi Kwath.

**2]Control Group:** In this group, 30 Patients of Madhumeha (DM) taking oral hypoglycemic drugs [i.e. Metformin +Sulfonylurea] advice by allopathic expert.

**Dietary advices:** Experimental group & Control group was advised to take standard diabetic diet. According to Ayurvedic texts and modern medical science.

**Diagnostic criteria :**

1) Patient having BSL fasting > 126 mg/dl and PP > 200 mg/dl or diagnosed by diabetologist.
2) Prabhootmutrata, Aavilmutrata and Naktamutrata.

**Inclusive Criteria :**

- Patient irrespective of sex.
- Patients of age group >16 years.
- Patient having Type II DM.
- Patient already on oral hypoglycemic drugs were included. [I.e. Metformin +Sulfonylurea].

**Exclusive Criteria :**

- Patients not willing for trial.
- Type I DM
- IHD complications
- Diabetic nephropathy
- Diabetic gangrene
- Autonomic neuropathy - Gastro intestinal problems.
- Severe peripheral neuropathy - Sensory loss Motor loss.
- Having some critical illness like malignancy etc.

**Follow Up:**

Follow up of patients of both groups were taken for observation on 0, 7th, 14th, 21 th day.

Observational parameters including *Prabhootmutrata, Aavilmutrata, Naktamutrata* were recorded at each and every follow-up. Then relief of signs and symptoms of both groups were compared with each other.

Parameters :

Assessment of signs and symptoms were done by adapting suitable scoring method.

**1] *Prabhoota Mutrata*:**

| | Frequency / 24 hrs | Volume |
|---|---|---|
| 0 | 3 - 4 | Normal |
| 1 | 5 - 7 | Mild excessive |
| 2 | 8 - 10 | Moderate excessive |
| 3 | > 10 | Severe excessive |

**2] *Aavil Mutrata*:**

0 Crystal clear.
1 Faintly cloudy or hazy with slight turbidity.
2 Turbidity clearly present but news print can be read through the tube.
3 More turbidity and news print can't be read.

**3] *Nakta mutrata:***

0 - Frequency < 2 times / night

1 - Frequency 3 - 4 times / night

2 - Frequency 5 - 6 times / night

3 - Frequency >7 times / night

**LAB INVESTIGATION**:

| | | |
|---|---|---|
| 1) BSL: | Fasting | PP |
| 2) Urine sugar: | Fasting | PP |

Other investigation will be done if necessary.

**CRITERIA FOR ASSESSING THE RESULTS**

Proportionate change in abnormal BSL (PP) will be calculate and assess as below –

| Improvement in result | BSL (PP) | Sign and systems |
|---|---|---|
| Complete | Comes to normal level | 100% Relief |
| Marked | 25% more than normal level | > 75% Relief |
| Moderate | 50% more than normal level | 50 - 75% Relief |
| Mild | 75% more than normal level | 25 - 50% Relief |
| No | No reduction | < 25% Relief |

Note: 1) By considering BSL (pp) 200 mg/dl as 0%. 2) BSL (PP) of patient on day 0 as 100%.

**STATISTICAL ANALYSIS**

Patients were examined thoroughly and findings were recorded before, during and after completion of therapy. The objectives parameters of *prameha – Madhumeha* were taken as BSL-F, BSL-PP.
The most leading clinical features of *Prameha – Madhumeha* were taken as subjective parameters before analysis. These are *Naktamutrata, Prabhootmutrata, Aavilmutrata*. It was recorded in the form of qualitative data which was converted to quantitative form of the convenience of statistical analysis. As the sample size is small, student't' test applied to determine the significance of improvement in symptoms. The

level of significance was set 5% $P < 0.05$ $t_{calculated} > t_{table}$ indicates significance of findings. Unpaired't' test applied to compare the effectiveness of both groups and to determine the superiority of the treatment.

**Mean improvement in BSL (F) during treatment**

| Group | 0th day (mg/dl) | 7th day (1-F/U) (mg/dl) | 14th day (2-F/U) (mg/dl) | 21st day (3-F/U) (mg/dl) |
|---|---|---|---|---|
| Trial | 179.2 | 162.9 | 146.6 | 130.7 |
| Control | 209.5 | 198.9 | 188.1 | 176.9 |

**Mean improvement in BSL (PP) during treatment**

| Group | 0th day (mg/dl) | 7th day (1-F/U) (mg/dl) | 14th day (2-F/U) (mg/dl) | 21st day (3-F/U) (mg/dl) |
|---|---|---|---|---|
| Trial | 272.9 | 251.8 | 230.9 | 212.3 |
| Control | 250.5 | 240.5 | 229.8 | 219.8 |

When both groups were compared for BSL (F) & BSL (PP), it was found that, Trail group treatment was significant Control group

**1) PRABHOOT MUTRATA**

**A) Table showing the effect of therapy on *Prabhoot Mutrata* in Trial group (recorded before and after treatment).**

| | Mean | S.D. | S.E. | T | P | ttable |
|---|---|---|---|---|---|---|
| **BT-AT** | **2.00** | **0.53** | **0.095** | **20.85** | **P<0.05** | **2.05** |

In Trial group value of $t_{calculated}$ is more than $t_{table}$. So the effect of therapy is significant on *Prabhoot Mutrata.*

**B) Table showing the effect of therapy on *Prabhoot Mutrata* in Control group (recorded before and after treatment).**

| | Mean | S.D. | S.E. | T | P | ttable |
|---|---|---|---|---|---|---|
| BT-AT | 1.53 | 0.51 | 0.092 | 16.55 | P<0.05 | 2.05 |

In Control group value of $t_{calculated}$ is more than $t_{table}$. So the effect of therapy is significant on *Prabhoot Mutrata*.

**B) Table showing comparison of effect of therapy on *Prabhoot Mutrata* in Trial group and control group before and after treatment ('unpaired't' test).**

| | Mean | S.D. | S.E. | t | P | ttable |
|---|---|---|---|---|---|---|
| T-C | 0.47 | 0.52 | 0.13 | 3.50 | 0.05 | 2.05 |

In Trial group and control group $t_{calculated}$ is more than $t_{table}$. So the effect of therapy given in Trial group is more effective than control group.

**2) AAVILAMUTRATA**

**A)Table showing the effect of therapy on *Aavilamutrata* in Trial group (recorded before and after treatment).**

| | Mean | S.D. | S.E. | t | P | ttable |
|---|---|---|---|---|---|---|
| BT-AT | 1.8 | 0.61 | 0.11 | 16.16 | P<0.05 | 2.05 |

In Trial group value of $t_{calculated}$ is more than $t_{table}$. So the effect of therapy is significant on *Aavilamutrata.*

**B) Table showing the effect of therapy on *Aavilmutrata* in Control group (recorded before and after treatment).**

| | Mean | S.D. | S.E. | t | P | ttable |
|---|---|---|---|---|---|---|
| BT-AT | 1.27 | 0.52 | 0.09 | 13.32 | P<0.05 | 2.05 |

In Control group value of $t_{calculated}$ is more than $t_{table}$. So the effect of therapy is significant on *Aavilmutrata*

**C) Table showing comparison of effect of therapy on *Aavilmutrata* in Trial group and control group before and after treatment ('unpaired't' test).**

| | Mean | S.D. | S.E. | T | P | ttable |
|---|---|---|---|---|---|---|
| T-C | 0.53 | 0.57 | 0.15 | 3.64 | P<0.05 | 2.05 |

In Trial group and control group $t_{calculated}$ is more than $t_{table}$. So the effect of therapy given in Trial group is more effective than control group.

**3] NAKTAMUTRATA**

**A) Table showing the effect of therapy on *Naktamutrata* in Trial group (recorded before and after treatment).**

| | Mean | S.D. | S.E. | T | P | Ttable |
|---|---|---|---|---|---|---|
| BT-AT | 1.87 | 0.59 | 0.10 | 16.95 | P<0.05 | 2.05 |

In Trial group value of $t_{calculated}$ is more than $t_{table}$. So the effect of therapy is significant on *Naktamutrata*.

**B)Table showing the effect of therapy on *Naktamutrat*a in Control group (recorded before and after treatment).**

| | Mean | S.D. | S.E. | T | P | ttable |
|---|---|---|---|---|---|---|
| BT-AT | 1.5 | 0.51 | 0.09 | 16.16 | P<0.05 | 2.05 |

In Control group value of $t_{calculated}$ is more than $t_{table}$. So the effect of therapy is significant on *Naktamutrata*

**C) Table showing comparison of effect of therapy on *Naktamutrata* in Trial group and control group before and after treatment ('unpaired't' test).**

| | Mean | S.D. | S.E. | t | P | ttable |
|---|---|---|---|---|---|---|
| T-C | 0.33 | 0.55 | 0.14 | 2.34 | P<0.05 | 2.05 |

In Trial group and control group $t_{calculated}$ is more than $t_{table}$. So the effect of therapy given in Trial group is more effective than control group.

**4) URINE [FASTING]:**

**A) Table showing the effect of therapy on urine (Fasting) in Trial group (recorded before and after treatment).**

| | Mean | S.D. | S.E. | tcal. | P | ttable |
|---|---|---|---|---|---|---|
| BT-AT | 1.87 | 0.43 | 0.079 | 23.54 | P<0.05 | 2.05 |

In Trial group value of $t_{calculated}$ is more than $t_{table}$. So the effect of therapy is significant on Urine (Fasting).

**B) Table showing the effect of therapy on urine (Fasting) in Control group (recorded before and after treatment).**

| | Mean | S.D. | S.E. | tcal. | P | ttable |
|---|---|---|---|---|---|---|
| BT-AT | 1.47 | 0.57 | 0.10 | 14.06 | P<0.05 | 2.05 |

In Control group value of $t_{calculated}$ is more than $t_{table}$. So the effect of therapy is significant on urine (Fasting).

**C) Table showing comparison of effect of therapy on urine (Fasting) in Trial group and control group before and after treatment ('unpaired't' test).**

| Groups | Mean | S.D. | S.E. | tcal. | P | Ttable |
|---|---|---|---|---|---|---|
| T-C | 0.4 | 0.51 | 0.13 | 3.054 | P<0.05 | 2.05 |

In Trial group and control group $t_{calculated}$ is more than $t_{table}$. So the effect of therapy given in Trial group is more effective than control group.

**5) URINE [POST PRANDIAL]:**

**A) Table showing the effect of therapy on urine (PP) in Trial group (recorded before and after treatment).**

| | **Mean** | **S.D.** | **S.E.** | **tcal.** | **P** | **ttable** |
|---|---|---|---|---|---|---|
| BT-AT | 2.03 | 0.76 | 0.14 | 14.56 | P<0.05 | 2.05 |

In Trial group value of $t_{calculated}$ is more than $t_{table}$. So the effect of therapy is significant on Urine (PP).

**B) Table showing the effect of therapy on urine (PP) in Control group (recorded before and after treatment).**

| | **Mean** | **S.D.** | **S.E.** | **tcal.** | **P** | **ttable** |
|---|---|---|---|---|---|---|
| BT-AT | 1.56 | 0.50 | 0.09 | 17.02 | P<0.05 | 2.05 |

In Control group value of $t_{calculated}$ is more than $t_{table}$. So the effect of therapy is significant on urine (PP).

**C) Table showing comparison of effect of therapy on urine (PP) in Trial group and control group before and after treatment (unpaired‘t’ test).**

| Groups | **Mean** | **S.D.** | **S.E.** | **tcal.** | **P** | **Ttable** |
|---|---|---|---|---|---|---|
| T-C | 0.46 | 0.64 | 0.16 | 2.79 | P<0.05 | 2.05 |

In Trial group and control group $t_{calculated}$ is more than $t_{table}$. So the effect of therapy given in Trial group is more effective than control group.

**5) BSL[fasting]:**

**Table showing comparison effect of treatment on BSL (Fasting) in Trial group and Control group (unpaired ‘t’ test applied).**

| Groups | **Mean** | **S.D.** | **S.E.** | **tcal.** | **P** | **ttable** |
|---|---|---|---|---|---|---|
| T-C | 15.93 | 8.34 | 2.15 | 7.40 | P<0.05 | 2.05 |

‘t’ calculated > ‘t’ table, so Trial group treatment is superior significant than control group treatment.

**6) BSL[POST PRANDIAL]:**

**Table showing comparison effect of treatment on BSL (PP) in Trial group and Control group (unpaired‘t’ test applied).**

| Groups | **Mean** | **S.D.** | **S.E.** | **t** | **P** | **ttable** |
|---|---|---|---|---|---|---|
| T-C | 29.9 | 13.62 | 3.51 | 8.50 | P<0.05 | 2.05 |

‘t’ calculated > ‘t’ table so Trial group treatment is superior significant than control group treatment.

**Overall effect of therapy as per expected result**

| Improvement | Trial Group Percentage of patients | | Control Group Percentage of patients | |
|---|---|---|---|---|
| | BSL (PP) | Relife in Sign & Symptoms | BSL(PP) | Relife in Sign & Symptoms |
| Cured | 18 (60.00%) | 19 (63.33%). | 12 (40.00%) | 10 (33.33%) |
| Marked | 5 (16.66%) | 9 (30%). | 5 (16.66%) | 7 (23.33%) |
| Moderate | 4 (13.33%) | 2 (6.66%) | 7 (23.33%) | 12 (40.00%) |
| Mild | 2 (6.66%) | 0 (0.00%) | 4 (13.33%) | 1 (3.33%) |
| No | 1 (3.33%) | 0 (0.00%) | 2 (6.66%) | 0 (0.00%) |
| Total | 30 (100%) | 30 (100%) | 30 (100%) | 30 (100%) |

## DISCUSSION

- This study was aimed to assess the efficacy of Guduchi- Tinospora cardifolia in management of Mahdumeha in comparison with conventional modern treatment.
- 60 Patients were randomly selected and divided. Experimental group A was treated with Guduchi kwatha in continuation with previous oral hypoglycemic drugs (Metformin 500 mg + sulphonylurm group B was treated with oral hypoglycemic drugs only.
- Each group of patients were advised a standard diabetic diet.
- Prevalence of Madhumeha was found more in 40-60 years age groups, mostly in service persons and businessman's having family history of madhumeha, kaphavata and kaphapitta prakruti.
- Due to analyse the result of both experimental groups and control group, paired't' test was applied and comparison of results of both groups were assessed by applying unpaired't' test at 5% significance level.
- It showed that BSL (F), BSL (PP), Urine (F), Urine (PP), Prabhootmutrata, Aavil mutrata, Naktamutrata, were significantly reduced in both experimental group A and control group B.
- Comparison of both treatments shows that treatment of experimental groups A were significantly effective than that of control group B in case of BSL (F), BSL (PP), Urine (F), Urine (PP), Prabhootmutrata, Availamutrata, Naktamutrata

After complete assessment it was found that experimental group A-18 patients were improved and comes to normal level were markedly improved, 4 were moderately improved, 3 were mildly improved and 1 has no improvement. In control group 12 patients were improved, 5 were markedly improved, 7 were moderately improved, 4 were mildly improved and 2 patients had no improvement.

## FUTURE SCOPE

- Multi centric trial can be carried out with larger sample size.
- Future additional studies may be performed to try Guduchi Kwath with Shodhan therapy e.g. Virechan to Control Hyperglycemia without oral Hypoglycemic drugs.
- Further additional studies may be performed to try guduchi kwath with parameters like HbA1C.

## MODE OF ACTION OF DRUG

### A] Ayurvedic Mode:

Guduchi is Tikta, Kashay rasatmaka, mainly madhur-vipak, ushna-veerya, guru, snigdha-guna with Tridoshamak, Deepan and Pachan. It acts as Vrushya means destroy the shukra dushti ultimately ojodusthi and Rasayani having dhatu balyakara. So if we concentrate on the pathology of Madhumeha, these properties acts against the properties of dushta and dravaguna kapha and also dushya vata causing prakopa so step of basic pathology can stop. Due to their ushna veerya and deepan pachana gunas, the dhatvagnimandhya due to dushta kledaka kapha can get back normal of agni's function. So there is normally forming of Ahara rasa with normally dhatu poshana. Ultimately causes next functions normally with avoiding Kledavriddhi. As it is Rasayana in nature, it helps to recover the dhatukshaya and ojakshaya because of dhatupushti.

### B] Modern Mode of Action:

The antidiabetic activity of Guduchi is may be due to increased entry of glucose into peripheral tissue and organ like liver. Guduchi increase the activity of glycogen synthesis in the liver, it may increase storage of glucose in hepatocyte. It also decrease the activity of phosphorylase in the liver, thereby it prevent release of glucose into the blood

## CONCLUSION

- After analyzing all the data and observations, it was concluded that *Guduchi kwatha* used in experimental group A along with oral hypoglycemic drugs shown significant results as compared to only oral hypoglycemic drugs used in control group-B.
- Statistically significant effect of *Guduchi kwatha* on *Prabhootmutrata*, *Aavilmutrata and Naktamutrata* as compared to control group B was may be due to.
    - Correction of *dushta kleda-utppati* which is responsible for above said *lakshanas in samprapti*.
    - The drug also may act at *mulasthana of mutravaha strotas* which are *meda/ vapavahan*. The therapy is safe.
- Though *madhumeha* is described *asadhya* in Ayurvedic classics, if once sets in, the complication of diabetes mellitus and side effects of the long term uses of modern oral hypoglycemic agents can be controlled or prevented with the best use of this Ayurvedic formulations.

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