How to Cite:

Comparative Evaluation of Efficacy of Haridradigana Yoga Basti with Haridradigana Ghana Vati and Metformin in the Management of Diabetes Mellitus Type II (Prameha) – A study Protocol

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Abstract---Prameha is one of the very common ailments or disorders which people are facing from a period of time. It is increasing day by day and passing on from generation to generations. Because it is a disorder occurring due to changes in habits, diet and sedentary lifestyle. Basically, in this disorder there is involvement of vitiated Vata and Kapha. In this there is a Avarana of Vata Dosha on Kapha Dosha. For Vitiated Vata Dosha Basti Karma is considered as highly appreciable and effective and Kapha-Ghana herbs should be used as a medicinal purposes to counter Vitiated Kapha Dosha. In this study Haridradi Gana is selected for Yoga Basti as this Gana possess Kapha ghana properties. Basti procedure is selected as it is ultimate solution of vitiated Vata Dosha. Along with this, Vati prepared by same
Haridradigana will also be prescribed to the patients followed by Basti Karma to improve its effectiveness and efficacy. The primary objectives of this study is to assess the efficacy of Haridradi Gana Yoga Basti with Haridradi Ghana Vati over objective parameters i.e. Blood sugar levels (Fasting & Post Prandial), Urine Sugar level, HbA1c in patients with Diabetes Mellitus Type II, to assess the efficacy of Metformin over objective parameters i.e. Blood sugar levels (Fasting & Post Prandial), Urine Sugar level, HbA1c in Diabetes Mellitus Type II & to compare the efficacy of Haridradigana Yoga Basti with Haridradigana Ghana Vati and Metformin over objective parameters i.e. Blood sugar levels (Fasting & Post Prandial), Urine Sugar level, HbA1c in Diabetes Mellitus Type II. A total of 60 patients will be enrolled by randomly dividing them equally into 2 groups i.e. Tab.Metformin will be prescribed to Group A (Control) for consecutive 45 days & Yoga Basti with Haridradi Gana (8 days) followed by Haridradigana Ghana Vati for Group B (Trial Group) for 37 day. Changes in the objective parameters i.e., Fasting and Post Prandial Blood Sugar Level, Urine Sugar Level, HbA1c will be observed and recorded. Results and conclusion will be drawn according to the data obtained in case registration and follow up forms.

**Keywords:** Prameha, diabetes mellitus type II, Yogvasti, Hardidradi Gana, Metformin.

**Introduction**

Diabetes mellitus (DM) is a metabolic condition caused by a problem with insulin secretion, action, or both. Insulin insufficiency causes chronic hyperglycemia, resulting in problems with carbohydrate, lipid, and protein metabolism\(^1\). Changing eating routine propensities, way of life change, uneven eating regimen, abundance inexpensive food, absence of activity are the purposes for improvement of development of diabetes and it’s root is in urbanization. According to the International Diabetes Federation (IDF), the number of persons with type 2 diabetes mellitus (T2DM) in the globe will rise to 552 million by 2030, more than doubling from 2000\(^2\). In Ayurvedic texts, Prameha shows identical Characteristic features which is observed with syndrome of Diabetes Mellitus. Premeha is a syndrome that encompasses all clinical diseases marked by an increase in urine volume, either with or without an increase in micturition frequency. The two most prominent symptoms of its sick state are polyuria and turbidity of urine\(^3\). Oral hypoglycemic specialists and insulin utilized for the treatment of diabetes mellitus by the allopathic arrangement of medication have various incidental effects. Ayurveda due to its comprehensive methodology not just intends to accomplish severe glycemic control yet in addition treat underlying driver of the infection.

**Background and rationale**

In Ayurveda, Acharya Charaka has additionally grouped Prameha under; Sthula (Obese) and Krisha (Asthenic) based on body constitution; while Acharya Sushruta
has grouped it under; Sahaja (Genetic) and Apathya Nimitta (Acquired) based on etiological factor included. Sthula Pramehi and Apathya Nimitta Pramehi gives the brief look at Type 2 diabetes so we can associate it with NIDDM where weighty food and inactive way of life are the causative components. Vagbhatta has arranged Madhumeha into two classifications as Dhatukshayajanya Madhumeha and Avaranajanya Madhumeha. The variables which incite Vata straightforwardly cause Apatarpanajanya Madhumeha and the variables which incite Kapha also, Pitta cause Santarpanajanya Madhumeha. In the previous kind the patients are generally asthenia can be connected with Type I DM and in the last kind patients are stout and can be likened with Type II DM⁴. Evasion of neatness and exercise, extravagance in resting, lying and stationary propensities and whatever different variables are probably going to increment Kapha, fat and pee are the causative components of Prameha. As per the Modern science, two kind of Diabetes are alluded to as type I (insulin subordinate) and type II (noninsulin subordinate).

Diabetes Mellitus is a gathering of metabolic infection, described by Hyperglycemia coming about because of deformities in insulin discharge, insulin activity or both. Typically, blood glucose level is firmly constrained by insulin, a chemical created by the Pancreas. In patients with diabetes, the nonappearance or lacking creation of insulin causes hyperglycemia. It modifies digestion of Carbohydrate, proteins and fat in the body. It is portrayed by undeniable degree of blood glucose and ensuing discharges through pee. The main side effects of established hypoglycemic drugs consists of weight gain, gastrointestinal (GI) disturbances, liver injury, hypersensitivity reactions, flatulence, diarrhoea and abdominal bloating etc⁵. Ayurveda regards patient as entire and never treats sickness yet unhealthy one. So here we are putting venture forward to discover protected and viable medication to control diabetes with having no incidental effect. Based on a thorough evaluation of the literature, herbal pharmaceutical interventions and Panchakarma procedures, as well as lifestyle changes, have been demonstrated to be helpful and safe in the treatment of diabetes mellitus. Considering the limitations & side effects of the conventional treatment options for DM, it becomes highly imperative to search some alternative but safe and effective treatment modalities in Ayurveda. Ayurveda can give better administration to Prameha without unsafe incidental effects. In Ayurveda, 20 kinds of Prameha and is a sub-sort of Vatika Prameha. The Vata might be incited either straight by its etiological factors, by Avarana of Kapha and Pitta to Vayu or by Dhatukshaya. More emphasis should be given over Bastichikitsa among Panchakarama having multi-dimensional therapeutic approach and its non–invasive nature as compared to Vamana and Virechana. Haridradi Gana possess Kapha-medho Ghana properties that is described in Ashtangaharidya Sutrasthana ShodhanadiganasangrahniyeAdhaya⁶. Properties of each drug of Haridradigana is mentioned in table no.1. This study will compare the efficiency of Haridradigana Yoga Basti with Haridradigana Ghana Vati with Metformin in the management of diabetes mellitus type II in order to discover a new combination of Ayurvedic herbs in the current era of ever-growing diabetes mellitus.

**Aims and objectives**

**Aim:** Evaluation of the comparative efficacy of Haridradigana Yoga Basti with Haridradigana Ghana Vati and Metformin in the management of Diabetes Mellitus Type II (Prameha).
**Objectives:**
- To assess the efficacy of *Haridradigana Yoga Basti* with *Haridradigana Ghana Vati* over objective parameters i.e. Blood sugar levels (Fasting & Post Prandial), Urine Sugar level, HbA1c in Diabetes Mellitus Type II
- To assess the efficacy of Metformin over objective parameters i.e. Blood sugar levels (Fasting & Post Prandial), Urine Sugar level, HbA1c in Diabetes Mellitus Type II
- To compare the efficacy of *Haridradigana Yoga Basti* with *Haridradigana Ghana Vati* and Metformin over objective parameters i.e. Blood sugar levels (Fasting & Post Prandial), Urine Sugar level, HbA1c in Diabetes Mellitus Type II

**Material and Methods**

**Study Type:** Interventional Study

**Trial design:**
Superiority clinical trial i.e. A randomized control trial (RCT) – Randomized reference standard control open clinical trial

**Case definition**- Diagnosed cases of Prameha (Diabetes Type II)

**Diagnostic Criteria**
Objective parameters:
- Fasting and Post Prandial Blood Sugar Level.
- Urine Sugar Level
- HbA1c

**Research question**

Whether *Haridradigana Yoga Basti* with *Haridradigana Ghana Vati* is more efficacious than standard control drug Metformin in the management of Diabetes Mellitus Type II (*Prameha*)?

**Ethics and dissemination:** Institutional Ethical clearance certificate, obtained with Ref No. MGACH/ IEC/ Oct 2020/128 dated 24.07.2021. CTRI registration is under process.

**Methodology**

**Study Setting:** The study will be conducted in Panchakarma OPD & IPD, Mahatma Gandhi Ayurveda College Hospital and Research Centre (MGACH&RC), Salod (Hirapur) Wardha, Maharashtra.

**Eligibility criteria**

Inclusion criteria:
- Patients with either sex having age between 20 -60 years
- Patients recently diagnosed for uncomplicated NIDDM (type 2 diabetes) and having
Fasting blood sugar level ≥126 mg/dl
Post meal blood sugar level ≥140 mg/dl
HbA1c ≥ 6.5

- Old cases of type-2 DM not taking any other anti-hypoglycaemic drugs
- Diabetic Patients suffering from Controlled Hypertension (Blood Pressure not more than ≥140 mmHg or an average Diastolic Blood Pressure not more than ≥90 mmHg)
- Patients willing to give informed consent
- Patient fit for Basti Karma as per the Ayurvedic classics

**Exclusion criteria**

- Patients with insulin-dependent diabetes mellitus (IDDM) and Type 2 diabetes who are on insulin therapy
- Patients suffering from Juvenile Diabetes or Gestational diabetes (ICD – 10 criteria 024)
- DM with complications e.g. Retinopathy, Nephropathy, neuropathy ,previous history of coma
- Patients suffering from any current acute illness, uncontrolled hypertension

**Interventions**

- Group A(Control)- Tab. Metformin
- Group B(Trial): Yoga Basti with Haridradi Gana (8 days) followed by Haridradigana Ghana Vati

*Methodology:* Methodology of the study is depicted in table no.4. The Study design is given in figure no.1

**Criteria for discontinuing or modifying allocated interventions:**

- Patients willing to quit in between will be allowed to quit and will be replaced.
- If patient develops any acute illness during the trial which may hamper the study.
- Withdrawn patients will be replaced.
- If any untoward incidence, features of drug sensitivity or any other disease or problem arises, the subject will be offered free treatment till the problem subsides.

*Follow up:* 45th day, 90th day

**Assessment Criteria**

Objective parameters:
- Fasting and Post Prandial Blood Sugar Level.
- Urine Sugar Level
- HbA1c
Outcomes:

**Primary:** Primary outcome is reduction in clinical features related to Prameha (Diabetes Type II)

**Participant timeline:** Total 90 days with follow up on 45th and 90th day.

Methods: Assignment of interventions (for controlled trials)
Total Sample size- 60 Patients (30 in each group) [considering 10% drop out in each group]

Data collection, management, and analysis methods

Observations will be made after completion of study, according to the data collected with the help of following:
- Case registration Form with detailed history and examination
- Follow Up Assessment Performa

Observations will be made according to the Data collected and subjected to statistical analyses to draw the results.

Data monitoring: The Data coding will be done by PI.

Statistical methods: Data obtained will be calculated by using Student’s Paired and Unpaired ‘t’ test. Data on continuous variables will be analysed using parametric tests. The data on discrete variables will be presented as (%). The continuous data will be presented as mean (SD)/Median (Min-Max).

Ap value of less than 0.05 will be considered as significant.

Consent: The written informed consent will be taken from the patient before starting the study. During the study the confidentiality of each patient will be maintained.
Figure 1. Flowchart of study design or methodology

Table 1
Properties/Rasapanchak of herbs of Haridradi Gana

<table>
<thead>
<tr>
<th>Serial No.</th>
<th>Drug</th>
<th>Rasa</th>
<th>Vipak</th>
<th>Virya</th>
<th>Guna</th>
<th>Mahabhuta</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Haridra</td>
<td>Katu, Tikta</td>
<td>Katu</td>
<td>Ushna</td>
<td>Laghu, Ruksha</td>
<td>Vayu, Agni, Akaash</td>
</tr>
<tr>
<td>2</td>
<td>Daruharidra</td>
<td>Tikta, Kashaya</td>
<td>Katu</td>
<td>Ushna</td>
<td>Laghu, Ruksha</td>
<td>Vaayu, Akaash, Prithvi</td>
</tr>
<tr>
<td>3</td>
<td>Yashtimadhu</td>
<td>Madhura</td>
<td>Madhura</td>
<td>Sheeta</td>
<td>Guru, Snigdha</td>
<td>Pruthvi, Jala</td>
</tr>
<tr>
<td>4</td>
<td>Prushnaparni</td>
<td>Madhura, Kashaya</td>
<td>Madhura</td>
<td>Sheeta</td>
<td>Laghu, Snigdha</td>
<td>Pruthvi, Jala</td>
</tr>
<tr>
<td>5</td>
<td>Indrauyava</td>
<td>Tikta, Kashaya</td>
<td>Katu</td>
<td>Ushna</td>
<td>Laghu, Ruksha</td>
<td>Vayu, Akaash</td>
</tr>
</tbody>
</table>
Table 2
Methodology of the study

<table>
<thead>
<tr>
<th>S.N.</th>
<th>Head</th>
<th>Group A (Control)</th>
<th>Group B (Trial)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sample size</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>2</td>
<td>Intervention</td>
<td>Tab. Metformin</td>
<td>Yoga Basti with Haridradigana Followed by Haridradigana Ghana Vati</td>
</tr>
<tr>
<td>3</td>
<td>Duration of treatment</td>
<td>45 days (1½ Months)</td>
<td>8 days, 37 days</td>
</tr>
<tr>
<td>4</td>
<td>Schedules</td>
<td>1-90 days</td>
<td>1st day Anuvasana Basti 2nd day Niruha Basti Alternate</td>
</tr>
<tr>
<td>5</td>
<td>Follow up period</td>
<td>90th day</td>
<td>47th day</td>
</tr>
<tr>
<td>6</td>
<td>Total duration</td>
<td>90 days</td>
<td>8 days</td>
</tr>
<tr>
<td>7</td>
<td>Dose</td>
<td>500mg OD</td>
<td>Anuvasana Basti-60ml Niruha Basti-774ml</td>
</tr>
<tr>
<td>8</td>
<td>Preparation and Procedure</td>
<td>Tab. Metformin</td>
<td>1. Poorva Karma (a) Basti Dravya preparation (b) Snehana (c) Swedana</td>
</tr>
<tr>
<td></td>
<td></td>
<td>500mg Orally once a day</td>
<td>2. Pradhana Karma (a) The patient should lie in the Vama Parshva (Left Lateral) position. (b) The BastiNetra is then put into the Gudamarga (Anus), and the Basti Dravya is delivered in a slow and steady manner..</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3. Paschaat Karma (a) The patient is allowed to lie down for a few minutes in a supine position. (b) Snana (Bath) (c) Rasadi Samsarjana Karma</td>
</tr>
</tbody>
</table>

Discussion

According to Samprapti of Prameha, Dosha vitiation i.e. mainly Kapha takes place in Basti (Urinary Bladder) and it disturbs the Vata Dosha. Due to Vata Dosha, Kapha moves in whole body and induces Obstruction in Basti10. Under the Samprapti of Santarpanajanya Prameha or in Sthula Pramehi the vitiated Kapha
and Pitta deter the Path of Vata causing its incitement. Shodhana is the favoured decision for the disposal of Doshas. Acharya Sushruta has especially referenced that in Prameha the vitiated Doshas stays arranged in the lower some portion of the body inferable from the failure of different Dhamanis for example vessels. Avaranajanya Prameha, Kapha is the dominating Dosha while the significant Dushyas are Meda and Kleda. In Avaranajanya Samprapti the vitiated Kapha and Pitta hinder the way of Vata causing its incitement. Samshodhana is effective treatment for disposal of doshas. Vagbhata has referenced that Doshas ought to be wiped out through the closest section. The viability of treatment is evaluated dependent on alleviation in cardinal signs and side effects likewise glucose, lipid profile, and other bio-synthetic boundaries with Deha bala, Agni bala, and Chitta bala according to Charak. Basti Karma in highly indicated by ancient Acharyas to counter and pacify such vitiated VataDosha. Kapha Doshaghna herbs should be selected for Vasti to mitigate Kapha. In this study, Haridradi Gana is selected for Niruha Basti. All five drugs in Haridradi Gana have Kapha-Ghana properties as shown in table no.1. After Yoga Basti schedule completion, then Vati prepared by same Haridradigana will be given for oral administration. Haridradi Gana is an ideal blend of medications which can clear Agnimandya.

What’s more, do Sroto shodhana as most of the medications are Laghu in Paka and Ushna Veerya. The extremely subsequent stage in Samprapthi Vighatana is giving Preenana and Poshana. Haridradi Gana is having drugs like Prishniparni and Yashtimadhu which are Madhura Vipaka which does the last capacity. Usna Veerya Katu Vipaka drugs are known for Srotoshodhana, AgniVardhana, Ama Pachana, Vatanulomana. These credits helps in clearing the Sroto Sanga, trailed by Jataragni and Rasa Dhatwagni Vardhana which thus helps in Rasa dhatu and its Upadhatu Nirmana and Poshana. So, use of Haridradigana through both Anal& oral routes will enhance the Kapha-Medoghana effect of the therapy. The probable mode of action of each drug in HaridradiGana based on their Anti-diabetic properties can be justified as follows:

Haridra (Curcuma longa): Curcumin reduces blood glucose and glycosylated haemoglobin levels by inhibiting hepatic glucose production and glycogen synthesis and stimulates glucose absorption by raising the expression of the genes Glucose Transporter1,Glucose Transporter2, and Glucose Transporter3. In Ayurvedic writing, powder of Haridra is exhorted in diabetes alongside Amlaki churna and nectar. It ends up being better dietary enhancement of high likely when utilized with milk. Curcuminoids lower lipid peroxidation by keeping up with the exercises of cancer prevention agent proteins like superoxide dismutase, catalase and glutathione peroxidase at more significant level. Curcuma longa contains curcuminoids, glycosides, terpenoides and flavanoides. Maximal hindrance of Human Pancreatic Amylase (HPA) was gotten from isopropanol remove what’s more, CH3)2CO remove which diminishes starch hydrolysis.

Daruharidra (Berberis aristata): The anti-hyperglycemic activity of Daruharidra root extract and its involvement in carbohydrate metabolism were investigated in diabetic rats, and it was discovered that it dramatically decreases blood glucose without having any hypoglycemic effect on their control counterparts.
Yashtimadhu (Glycyrrhiza glabra): The diabetogenic effects of streptozotocin were significantly improved by glycyrrhizin treatment, which modulated blood glucose levels, glucose intolerant behaviour, decreased serum insulin levels, including pancreatic islet cell numbers, increased glycohaemoglobin levels, and increased cholesterol and triglyceride levels\(^{20}\).

Prushnaparni (Uraria picta): The amount of U. picta given to the animals on a regular diet significantly improved their glucose clearance rates. Future studies should look at the increased quantity because the insulin sensitivity of plant extracts is yet unknown\(^{21}\).

Indrauyava (Holarrhena antidysenterica): The effects of Indrayava extract on streptozotocin-induced diabetes in rats. Indrayava seeds reduced serum blood glucose levels in diabetic rats in 14 and 21 days, lowering glucose levels by 39.7% and 48.0%, respectively\(^{22-40}\).

Conclusion

Conclusion(s) will be drawn according to the observations made in the case registration and follow up forms on the various assessment parameters.

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