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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 ailment or disorder 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

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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 GroupB (Trial Group)for 37 day. Changes in the objective parameters i.e., Fasting and Post Prandial Blood Sugar Level, Urine Sugar Level, HbA1cwill 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 Nimittaja* (Aquired) based on etiological factor included. *Sthula Pramehi* and *Apathya Nimittaja 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 DM[4]. 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 etc[5]. *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 ShodhanadiganasangrahniyeAdhaya*[6]. 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[7]
  - Post meal blood sugar level ≥140 mg/dl
  - HbA1c ≥ 6.5[8]
- 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[9]

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 45thand 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). Apvalueoflessthan0.05willbeconsidered 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.

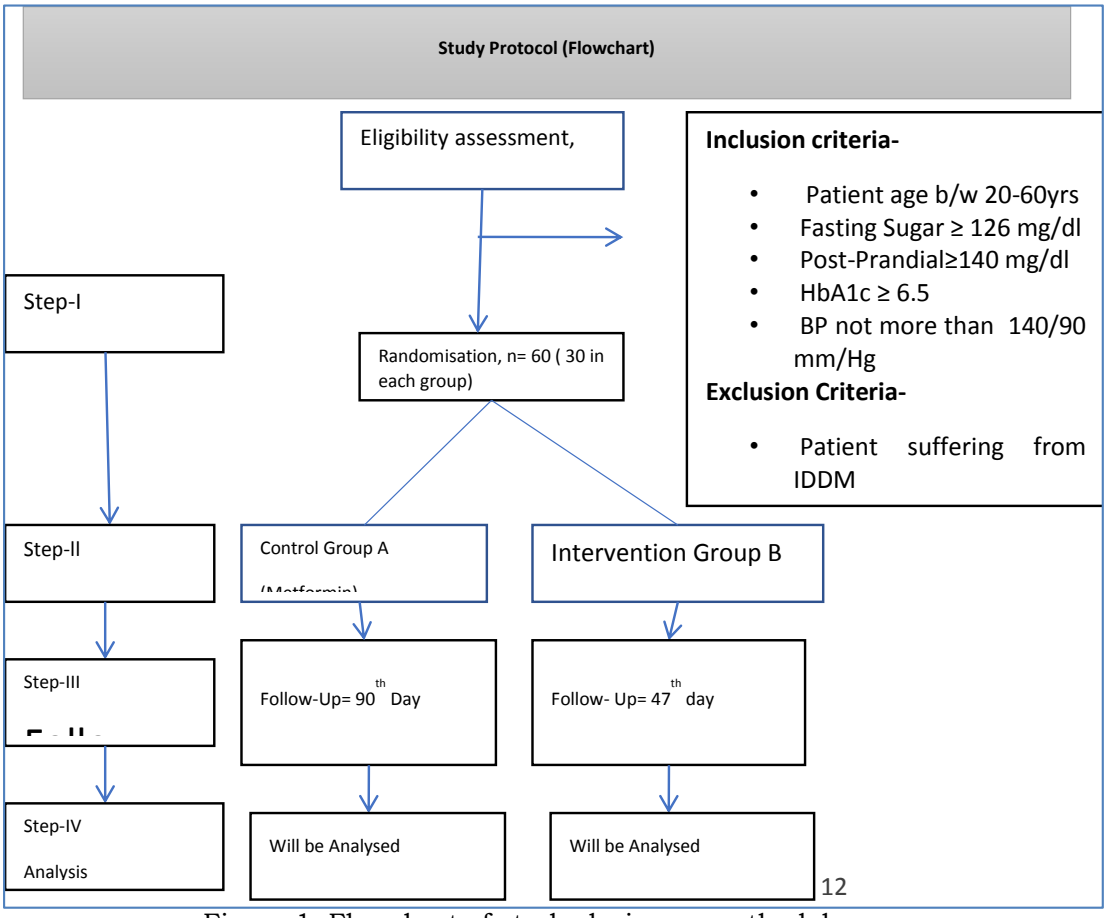

Figure 1. Flowchart of study design or methodology

Table 1
Properties/Rasapanchak of herbs of Haridradi Gana

Serial No.	Drug	*Rasa*	*Vipak*	*Virya*	*Guna*	*Mahabhuta*
1	*Haridra*	*Katu,Tikta*	*Katu*	*Ushna*	*Laghu,Ruksha*	*Vayu, Agni, Akaash*
2	*Daruharidra*	*Tikta, Kashaya*	*Katu*	*Ushna*	*Laghu,Ruksha*	*Vaayu, Akaash, Prithvi*
3	*Yashtimadhu*	*Madhura*	*Madhura*	*Sheeta*	*Guru,Snigdha*	*Pruthvi, Jala*
4	*Prushnaparni*	*Madhura, Kashaya*	*Madhura*	*Sheeta*	*Laghu,Snigdha*	*Pruthvi, Jala*
5	*Indrauyava*	*Tikta, Kashaya*	*Katu*	*Ushna*	*Laghu,Ruksha*	*Vayu, Akaash*

Table 2
Methodology of the study

S.N.	Head	Group A (Control)	Group B (Trial)
1	Sample size	30	30
2	Intervention	Tab. Metformin	*Yoga Basti with Haridradigana*Followed by *Haridradigana Ghana Vati*
3	Duration of treatment	45 days (1½Months)	8 days, 37 days
4	Schedules	1-90 days	1st day *Anuvasana Basti* 2nd day *Niruha Basti* Alternate
5	Follow up period	90th day	47th day
6	Total duration	90 days	8 days
7	Dose	500mg OD	*Anuvasana Basti*- 60ml *Niruha Basti*- 774ml[23]
8	Preparation and Procedure	Tab. Metformin 500mg Orally once a day	1. *Poorva Karma* (a) *Basti Dravya* preparation (b) *Snehana* (c) *Swedana* 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.. 3. *Paschaat Karma*[24] (a) The patient is allowed to lie down for a few minutes in a supine position. (b) *Snana* (Bath) (c) *Rasadi Samsarjana Karma*

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 *Basti*[10]. 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*[11]. 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[12]. 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[13]. *Basti Karma* in highly indicated by ancient *Acharyas* to counter and pacify such vitiated *VataDosha*[14]. *Kapha Doshaghna* herbs should be selected for Vasti to mitigate *Kapha*. In this study, *Haridradi Gana* [15]is selected for *Niruha Basti.* All five drugs in *Haridradi Gana* have *Kapha-Ghana* properties as shown in table no.1[16]. 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 *Prishniparn*i 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 glyacosylated 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[17]. 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 flavanoids. Maximal hindrance of Human Pancreatic Amylase (HPA) was gotten from isopropanol remove what's more, CH3)2CO remove which diminishes starch hydrolysis[18].

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[19].

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 (*Urariapicta): 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 (*Holarrhenaantidysenterica): 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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