



Comparative study on hypoglycemic activity of *Khadira Pooga vasti* and *Patikashaya* in *Madhumeha*: A study protocol

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Abstract

Background: As of 2015, an estimated 415 million people have diabetes worldwide, with type II DM making up about 90% of the cases. From 2012 to 2015, diabetes is estimated to have resulted in 1.5 to 5.0 million deaths each year which makes it one of the 4 leading causes of death. The level of morbidity and mortality due to diabetes and its potential complication are enormous and pose significant healthcare burdens on both families and society. Madhumeha is one of the 20 Pramehas, which comes under Vataj subtypes and is characterized by the sweet urine resembling Honey. Madhumeha is considered as Asadhya" owing to its chronicity and its nature of affecting deeper tissues. Diabetes is a metabolic syndrome characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both.

Aim and Objectives: to study the effect of *khadir pooga vasti* and *khadir pooga patikashaya* in *Madhumeha* and to observe the effect of *khadir pooga vasti* and *khadir pooga vasti* along with *patikashaya* on fasting blood sugar, post prandial blood sugar, urine sugar fasting and post prandial and glycosylated hemoglobin i.e HBA1C.

Methodology: In this study, 30 patients will be divided randomly into two groups (15 in each group). In Group A *Khadira pooga vasti* will be administered at morning time empty stomach. In Group B, *Khadira pooga vasti* (rectal enema) will be administered at morning time empty stomach, along with *patikashaya* of *Khadira* and *pooga* will be administered orally for 14 days.

Results: We will observe the changes in subjective as well as objective parameters.

Conclusion: *Khadira, pooga vasti* and *patikashaya* will be lowering the value of blood glucose.

Keywords: madhumeha, khadir, pooga, patikashaya, vasti

Introduction

Background and Rationale

The Diabetes Mellitus (DM) is a fast growing global problem with huge social, health and economic consequence and chronic metabolic disorder in nature. It is estimated that 61.3 million people live with diabetes in India (2011 estimates). This number is expected to increase to 101.2 million by 2030 [1]. *Madhumeha* (Diabetes Mellitus) is Non Insulin Dependent Diabetes Mellitus (NIDDM) is one among the *Vataja Prameha* [2]. It imitates DM, a way of life issue created by undesirable dietetics and routine. The world wellbeing frameworks are searching for a superior administration which is affordable and compelling. DM is an interminable metabolic issue. Is the current consuming issue all through the world influencing bigger populace which needs exceptional consideration as it is one the main sources inactive sitting, sleeping in, exorbitant utilization of curd, meat soup of the residential amphibian and muddy creatures and milk, milk shakes, new grains and results of jiggery. They all are *Kapha* advancing in nature [3].

There are huge quantities of medications comprised of natural and mineral starting point referenced in Ayurvedic messages, informed for the treatment with respect to *Madhumeha*. *Khadira* and *Pooga* blend is one among such. This plan as *Vasti* is one of the promising definition to battle

Madhumeha. They have hostile to diabetic (*Pramehaghna*) properties. *Samshodhana vasti* is the best module for the DM (*Madhumeha*) as it is started from *Kapha* and *Vata* [4].

Rationale of the Study

As the *Madhumeha* (DM) is increasing by prevalence and becoming a life threatening imparts the global attention in 21st millennium. *Ayurveda* a good old tradition has contributed many methods to combat this life style disorder. *Khadira Pooga Compound (KPC) Vasti* is another economic and effective management for the pre diabetic and diabetic affected is proposed here with the examples of the past. The main causative factor for diabetes is *vata and kapha*. *Vata* is the prime *dosha*. And for *vata dosha, vasti* is main treatment according to *vata* predominancy. For *kapha*, both drugs are *kashaya* in nature which will be helpful to break the pathophysiology of diabetes. Hence we selected the drugs for study to see the hypoglycemic effect on that basis.

Aim and Objectives

Aim

To provide an economical and effective hypoglycemic effect of *khadir pooga vasti* and *patikashaya* in *madhumeha*.

Objectives

To study the hypoglycemic effect of *Khadira Pooga Vasti* in *Madhumeha* (NIDDM)

1. To study the hypoglycemic effect of *Khadira pooga vasti* along with *Khadira pooga Patikashaya* in *Madhumeha* (NIDDM)
2. To compare the effect of *Khadira Pooga vasti* and *patakashaya* of *Khadir pooga* in *Madhumeha*

Criteria of Diagnosis

1. Subjective and Objective criteria meeting classical *Madhumeha* (DM)
2. FBS ranges from 110mg/dl up to 200mg/dl
3. PPBS ranges from 140mg/dl up to 300mg/dl
4. Post Prandial Blood Sugar Levels >200 mg/dl.
5. Glycosylated hemoglobin i.e. HbA1C >6.5%

Research Question

Whether *khadir pooga vasti* along with *patikashaya* is effective in *Madhumeha*?

Hypothesis: *Khadir pooga vasti* along with *patikashaya* is effective on *Madhumeha*.

Null Hypothesis: *Khadir pooga vasti* along with *patikashaya* doesn't effect on *Madhumeha*.

Trial Design: A randomized comparative interventional clinical study

Methodology

Study Setting

The study will be conducted in Ayurvedic academic hospital MGACH & RC, Salod (H), Wardha.

Table 1: Composition of the trail drug

Sr. No.	Sanskrita Name	Botanical Name
1.	<i>Khadira</i>	Acacia Catechu
2.	<i>Pooga</i>	Areca Catechu

Eligibility criteria

Inclusion Criteria

1. Patients suffering from the *Madhumeha* (ICD-10 criteria E11)
2. Either of Gender will be included
3. Age of the patients between 20 to 50 years.
4. FBS ranges from 110mg/dl up to 200mg/dl
5. PPBS ranges from 140mg/dl up to 300mg/dl
6. Patients with HbA1C value >6.5%.
7. Early Diabetic (onset of 2yr or 5 yr)

Exclusion criteria

1. Impaired glucose tolerance (ICD-10 criteria R73.0)
2. Pregnancy, childbirth and the puerperium (O24.-)
3. Glycosuria of NOS (R81) or renal (E74.8)
4. History of Ketoacidosis
5. Patients on insulin or steroid therapy
6. Patients with any major systemic diseases

Table 2: Interventions of both groups

Grouping	Group A	Group B
Sample size	15	15
Intervention	<i>Khadira pooga vasti</i>	<i>Khadira pooga vasti</i> along with <i>patikashaya</i> of <i>Khadira</i> and <i>pooga</i>
Duration of treatment	14 days	14 days
Timing of treatment	Morning (empty stomach)	Morning (empty stomach)
Follow up	14 days	14 days
Timing of treatment	Morning (empty stomach)	Morning (empty stomach)
Total duration	28 days	28 days

Criteria for discontinuing or modifying allocated interventions

If subjects will get adverse effect of medicine and if not ready for taking continue *vasti* for 14 days, Subjects will be discontinuing the trial. If adverse effects will get then subjects will offered free treatment till the issue dies down.

Follow up

14th days

Primary Outcomes

We will see the impact of *Khadira pooga vasti* and *Khadir pooga vasti* along with *khadira pooga patikashaya* on fasting and post prandial blood sugar, urine sugar fasting and post prandial. It is hypothesized that *Khadira pooga vasti* along with *khadira pooga patikashaya* will be more effective through *vasti*. We will compare the effect on *vasti* and *patikashaya* on Blood sugar and Urine sugar.

Secondary Outcomes

We will see the effect of *Khadira pooga vasti* and *khadira pooga vasti* along with *patikashya* of *khadira* and *pooga* on Glycosylated hemoglobin ie HBA1C.

Discussion

Madhumeha is among one of the type of 20 *Pramehas*, which comes under *Vataj* subtypes and is characterized by the sweet urine resembling Honey. *Madhumeha* is mentioned as a '*Asadhya*' owing to its chronicity and its nature of effecting deeper tissues. Diabetes is a metabolic syndrome characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Being an important tool for the control of *Vata*, *Vasti* can play a key role in the management of *Madhumeha*, which is one of the 4 types of *Vataj Prameha*. The present study has been selected from an untouched portion of Sushrut Samhita, Chikitsa Sthan 11 Chapter, named *Prameha Chikitsa*, where the drug *Khadir, Pooga* is indicated for *Prameha* in the form of *Vasti*. *Khadira* is mentioned as antihyperglycemic [5]. In Bangladesh, catechu ie *khadira* is used for treatment of diabetes and pain by the folk medicinal practitioners. May be the present chemical components named quercetin works as a antihyperglycemia reported to be present in *khadira* [6]. Flavonoids presented in the *khadira* are help to increase secretion of insulin and inhibit cyclooxygenase and lipoxygenase. Thus it possesses anti diabetic and anti-inflammatory effect [7].

Pooga

It has regulatory effects on blood glucose and lipids, etc [8]. It has a property like Hypoglycemic activity, Arecoline was investigated and reported to have hypoglycemic activity [9]. Hence according to their activity or actions on hypoglycemic *vasti* can be help to break pathogenesis of *madhumeha*. It nourishes and strengthens all the dhatus due to its properties [10].

Statistical Analysis

Data will be analyzed on the basis of appropriate statistics Paired t test, unpaired test and Non parametric test by using SPSS software.

Time Duration till Follow Up

28th days. Total treatment duration will be 14th days and after the treatment follow up will be 14th days.

Follow Up Period

14th days

Time Schedule of Enrolment, Interventions

Vasti and *vasti* along with *patikashaya* will be given for 0 to 14 days

Recruitment

15 (in each group) sample will be recruited by single randomizing sampling method.

Methods

Literature review search, plan of work, blue print, medicine collection, authentication of raw drugs, data collection, treatment and its effects will be observe.

Data Collection Methods

Randomized sampling

Objective Criteria

1. Fasting Blood Sugar
2. Post Prandial Blood Sugar (PPBS is collected after 2-hour PG after 75-gm OGTT)
3. Urine sugar Fasting and Post Prandial
4. Glycosylated hemoglobin i.e. HbA1C

Data Management

Data coding will be done by principal investigator.

Statistical Methods

Paired and unpaired for objective parameters, non-parametric for subjective parameters.

Ethics and Dissemination

Research ethical approval, after critical evaluation and presentation the ethical committee will approve the research topic.

Consent or Assent

Subjects will be given detail information regarding their treatment in their own language. Then written consent will be taken from patients before starting the study.

Dissemination policy

Will be in the form of paper publication and Monograph.

Informed consent materials

Subjects will be given all consent material in the form of hard copy and other related documents.

Strengths

If proposed study will results in the positive outcome then it will be established new mode of management for the *Madhumeha*. In society, we will be provided economical and effective hypoglycemic management for *Madhumeha*.

Limitations

Will be convincing the patients for *vasti*.

Conclusion

Conclusion will be mentioned after the analyzing the data.

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