



Study of the efficacy of *Tryushanadi gudika* in the management of *Prameha* with special reference to diabetes mellitus type II

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Abstract

Background: Prameha is a Tridoshaj, Kapha predominant disease. Acharya Charak, Sushruta and Vagbhata included it in Ashtamahagada. Madhumeha (Diabetes mellitus) is predominantly a Vatika disease. Due to similarities of sign and symptoms, Madhumeha can be correlated with Diabetes mellitus type II. Prabhutamutrata or avilmutrata are the clinical features of Madhumeha.

Aim: To evaluate the effectiveness of Tryushanadi gudika in the management of Prameha with special reference to Diabetes mellitus type II.

Material and Methods: 40 subjects (20 in each) will be classified randomly into 2 parallel groups. Group A i.e. Trial group - Tab. Metformin 500 mg will be given before meal two times a day with lukewarm water for 30 days and Group B i.e. Control group - Tryushanadi gudika 500 mg will be given before meal two times a day with lukewarm water for 30 days. Assessment will be noted on 0, 30th & 60th day.

Result: Variations will be seen in subjective as well as objective parameters and inferences.

Conclusion: The effectiveness of Tryushanadi gudika will be more than Tab. Metformin

Keywords: prameha, tryushanadi gudika, diabetes mellitus, madhumeha

1. Introduction

Background and rationale

The word 'Prameha' means *Prabhutamutrata* (Polyuria) or *Avilmutrata* (Turbid urine). *Prameha* is a *Tridoshaj*, *Kapha* predominant disease.^[1] It is included under *Ashtamahagada* by Acharya Charak, Sushruta and Vagbhata.^[2] *Madhumeha* (Diabetes mellitus) is described among the 20 sub types of *Prameha* and is predominantly a *Vatika* disease. The word 'Madhumeha' means a disease in which *mutra* attains similar property like *Madhu* (Honey).

It is a disease of *Medovaha Strotas* and mainly caused due to *Medodushiti*. This *Medodushiti* vitiates *Mansa*, *Rakta*, *Kleda* and *Ojas*. Thus *Rasa*, *Mansa*, *Meda dhatus*, *Mutra*, *Sweda* and all three *doshas* are involved in the *Samprapti* of *Prameha*^[3] Due to similarities of sign and symptoms, *Madhumeha* can be correlated with Diabetes mellitus type II. It is a disease caused by absolute or relative deficiency of Insulin having hyperglycemia^[4] Changing life style, lack of exercise, fast foods, improper diet and sedentary life are predisposing factors of it^[5].

Diabetes in its early stage is categorized as prediabetes and is a leading risk factor for diabetes.^[6] It is said that Prediabetes is one of the phases when the person is not being openly diabetic.^[7] The disorders of glucose intolerance are regarded as diseases of developing countries.^[8] About 415 million adults around the world are suffering from diabetes and it is estimated it will reach around 642 million by 2040.^[9] A number of herbal formulations are described in Ayurveda which are effective in the

management of *Prameha*. *Tryushnadi gudika*^[10] is one of them described in *Chakradatta*.

It contains *Amalaki* (*Emblica officinalis*.Burm), *Bibhitaki* (*Terminalia bellerica*.Roxb.), *Haritaki* (*Terminalia chebula*.Retz.), *Pippali* (*Piper longum*.Linn.), *Marich* (*Piper nigrum*.Linn.), *Sunthi* (*Ziziber officinalis*.Roxb.), *Guggul* (*Commiphora mukul*) and *Gokshur* (*Tribulus terrestris*.Linn.) *Madhumeha* is wild growing worldwide problem with massive economic, communal and well-being consequence.

Prevalence of *Madhumeha* is increasing due to unhealthy dietary habits and sedentary lifestyle.

It results in serious complications if not treated properly. Ultimately it affects the kidneys, eyes, heart, blood vessels & nerves.

Lifestyle modification or pharmacotherapy in such individuals becomes a clinical consideration.^[11] So to overcome such complications like diabetic foot, there is need to keep the blood sugar level within standard level.^[12] To reduce the burden of diabetes, implementation of preventive measures is needed.^[13] doctor aspects numerous trials to proposal diabetes maintenance and requires measurements for total actual and superiority maintenance of patient by type II diabetes mellitus^[14] Hence there is need to search the effective and safe herbal medicine. Metformin is an antihyperglycemic agent of the *biguanide* class, used as the first medication for the managing Diabetes mellitus type II.

A number of study is revealed on this topic *vataja kasa* in

the region of AVBRH and Wardha^[15-19] Hence this comparative study is planned to assess the effectiveness of *Tryushanadi gudika* with drug Metformin on Blood Sugar Level.

The aim is to assess the effects of *Tryushanadi gudika* on blood sugar level (Fasting and Post prandial), To assess the effects of *Tryushanadi gudika* on *Kshudhadhikya* (Increased appetite), *Naktamutrata* (Nocturnal micturition), *Kar-Pada Suptata* (Numbness) and *Hasta Pada Tala Daha* (Burning palms and soles),

To compare the effects of *Tryushanadi gudika* with Metformin on blood glucose level (Fasting and Post prandial).

Trial structure design

Randomized with Standard controlled Open labeled Double armed Study. Interventional study of two similar group set having equal ratio.

Interventions

Table 1

Drug with groups	Dose	Anupana	Time duration	Frequency	Special Precautions
Group A: <i>Tryushanadigudika</i>	500 mg	Lukewarm Water	Empty stomach (40min previous to lunch)	Twice a day	Avoid Sugar and sweet products
Group B: Tab.Metformin	500 mg	Lukewarm Water	Empty stomach (40min previous to dinner)	Twice a day	Avoid Sugar and sweet products

Standards for terminating and changing assigned interferences

Patient will be cancelled during the study if somewhat inconvenient occurrence, structures of medication sensitivity or any supplementary illness or problematic rises, free treatment.

Will be given to the patient and permitted till the problematic diminishes. We will measure number of medicines for the ingesting of appropriate dose for valuation and to check drug adherence, there will be the follow up throughout 30 days of treatment.

Follow up duration afterward treatment

30th & 60th day Patient will be recommended to avoid sugar and sweet products.

Primary Results

Assessment of the outcome of trial drug on Blood Glucose Level (Fasting & Post prandial) in the start and end of the treatment.

Secondary Results

We will see reoccurrence and ill consequence of trial drug.

Statistical study

The variations from starting point will be examined by applying Paired and Unpaired 't' Test for objective parameters. Mc Nemar's test for Frequency of the patient and Subjective criteria^[21].

Time Period Till Trail Ends

The subject will be observed throughout treatment of 30 days.

Follow up duration

0, 30th and 60th day

Methodology

Study location

The assessment of study will be directed in MGACH & RC, Salod (H), Wardha.

Eligibility standards

Age among 30 to 60 yrs of both gender and all Shareerik Prakriti, Patient with Fasting Blood Sugar Level ≥ 126 mg/dl and /or Post prandial Blood Sugar Level ≥ 200 mg/dl,^[20] Newly diagnosed patients are included.: Insulin Dependent Diabetes Mellitus (IDDM) and those who are under Insulin therapy, Pregnant and lactating women, Patient with Cirrhosis of liver, Pancreatitis, HIV, Hepatitis, Patients with acute complications like Hyperglycemia and Hypoglycemic Coma., Patient with chronic diabetic complications like Nephropathy, Neuropathy and Retinopathy are excluded.

Time period of registration, interferences

Drug will be administered from starting of the treatment to 30 days and after that follow up on 30th and 60th day.

Recruitment

40 (20 in each set) subjects will be recruited by simple random selection Lottery method, and PI will assign and register the subjects

Methods

Information gathering, organization, and examination

Data gathering techniques

Assesment parameters: Subjective Parameters- *Kshudhadhikya* (Increased appetite), *Naktamutrata* (Nocturnal micturition), *Kar-Pada Suptata* (Numbness), *Hasta Pada Tala Daha* (Burning palms and soles)

Objective Parameters - Blood Sugar Level (Fasting & Post prandial). The assesment will be done according to the gradations^[22] on 0th, 30th day (during trial) and On 60th day (end of the trial). We will be in contact with subjects by keeping mobile no. and time to time inform them to take medicine and follow up and information of follow up subjects will be kept in documents by motive.

Expected Result

Tryushanadi gudika will reduce *Kshudhadhikya* (Increased appetite), *Naktamutrata* (Nocturnal micturition), *Kar-Pada Suptata* (Numbness), *Hasta Pada Tala Daha* (Burning palms and soles) and reduce blood sugar level (Fasting and Post prandial) and give symptomatic and therapeutic relief.

Discussion

Triphala contains *Amalaki* (*Embllica officinalis*. Burm), *Bibhitaki* (*Terminalia belerica*. Roxb.), *Haritaki* (*Terminalia chebula*. Retz.) due to their *Laghu-Ruksha*

Properties reduces *Kleda* in the body that in turn modifies the *Dhatushaithilya*. Most of the drugs in the formulation are having *Tikta-Kashaya Rasa* which reduces *Madhurya* in the *Rasa, Rakta* and other *Jaliya Dhatu*. *Triphala* is a combination that is found to have a hypoglycaemic effect. *Trikatu* contains *Pippali* (*Piper longum*.Linn.), *Marich* (*Piper nigrum*.Linn.), *Sunthi* (*Ziziber officinalis*. Roxb.) have the *tikshna* (Pungent) and *ushna* (Hot) properties. With the help of these properties, *Lekhana* (Scrapping) of *kleda* and *kapha* from the *dhatu* was done. *Trikatu* acts by affecting the pathophysiology of *Prameha* by *Shodhana* (Cleaning) and *Chedana* (Removing) of *Kleda* and *Lekhana* (Scrapping) of *Kaphadosha* and *Medadhatu*. *Gokshur* (*Tribulus terrestris*.Linn.) is diuretic in nature. *Guggul* (*Commiphora mukul*) is one of best drug for *Mutravaha Srosta*, *Meda* and *Kapha Dosha*.

Data Management

The information entrance coding will be completed by PI

Statistical approaches

Paired 't' Test and Unpaired 't' Test for objective parameters. Mc Nemar's test for Frequency of the patient and Subjective parameters.

Ethics Moral and Distribution

Research ethics agreement and also endorsement from research ethics board has been reserved. Ref.No. DMIMS (DU)/IEC/Jun-2019/8026

Consent or Any Agreement

The on-paper consent will be obtained from the subject before beginning of the trial. Throughout the trial the privacy of individual subject will be preserved.

Dissemination strategy

The information will be disseminated by paper journal or publication. Authors eligibility strategies and any proposed use of specialized authors

Informed Agreement Resources

With complete material data model agreement consent form and any other associated certification will be allotted to subjects.

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