



Research Article

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EFFICACY AND CLINICAL SAFETY OF PRISHIPARNI GHANAVATI IN GESTATIONAL DIABETES MELLITUS (PRAMEHA IN GARBHINI)

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ABSTRACT

Aim: To study the efficacy and clinical safety of Prishniparni ghanavati in Gestational Diabetes Mellitus (Prameha in Garbhini). **Methodology:** The study was conducted on 20 patients, Prishniparni ghanavati 500 mg twice daily, with warm water. This study was conducted at Bharati Ayurveda hospital during 2020-2022. It was a randomized, open-control trial study. Patients with raised DIPSI (Diabetes in pregnancy societies of India), i.e., above 140 mg/dl and below 200 mg/dl, were included in this study. **Results:** A total of 31 patients were evaluated in this study. Out of which, 30 were recruited and 20 patients completed. A total of two patients dropped out due to factors like the covid-19 pandemic, irregular follow-up, etc. The herbal medicine was tolerated well in trial group patients. **Conclusions:** In this study, it is proved that prishniparni could be the choice of the herb in these cases. Prishniparni proved effective in managing GDM if the BSL is less than 200. All patients well tolerated the herb. The side effects are not observed in this study.

Key words: Prameha in Garbhini, Gestational Diabetes Mellitus

INTRODUCTION

The prime aim of Ayurveda is the maintenance of health. Various lifestyles (charya and paricharya) are mentioned to achieve this aim. Lifestyle, i.e., garbhini paricharya, is the maintenance of health during pregnancy.

Ashtanga has described
Anaupagataya - To avoid Garbha upaghata
Pairpuntvya - For full-term development of Garbha
Sukhprasavaya - Uncomplicated normal labour

While advising the essential diet and herbal intake, acharya has mentioned a few herbs. According to Acharya Sushruta¹, Prishniparni is the herb that is recommended in the 6th month of garbhini awastha. While studying this herb, it was found that Prishniparni is pramehaghna (antidiabetic). So, it is decided to explore its action as pramehaghna during the 24th to 28th weeks of pregnancy.

Ayurvedic classics were written 3000 - 5000 years ago. The tridosha theory, rasa, virya, vipaka theory, panchmahabhuta theory and even karyakaarana vada are all fixed theories applicable even today.² Various diseases are explained in these classical texts. Madhumaeha is given in Ayurvedic Samhitas, but the reference for Garbhini Prameha is challenging to get directly in ayurvedic Samhitas.

In Prameha, Aharaj hetu and mansika hetu are cited. In aharaj hetusevan Ati Madhur Ahara sevan is said to be the cause of Prameha. Similarly, in modern texts also for diabetes mellitus.

Charaka Samhita sharira sthana mentions that excessive intake of atimadhurpadartha by garbhini leads to pramehi, atisthul santati.³

The only reference from Bhaishajya Ratnawali⁴ quotes that excessive use of atimadhura, atiguru, paryushita ahara and atibhojna will lead to ojomaha in garbhini.

Oja is described as the bodily element which is an essence of all the seven dhatus in the body. In the sukshma pachana, when the poshaka shukra dhatu enters the shukra vaha strotas, it is acted upon by the shukra dhatvagni, which transforms it into stable or poshya shukra dhatu. Simultaneously a very minute, subatomic essence part is also produced, known as Oja. The nourishment and growth of the body, imparting of strength and the development of all body factors are influenced by the oja.⁵

Oja maintains bruhan. Considering the need for Oja maintenance during pregnancy, Acharya Vagbhata II has advised using jivaniya gana dravas for internal use.⁶ The intake of bruhan and Madhur is considered up to 3 months of pregnancy. If the quantity of bruhan and Madhur dravya is increased either by diet or by herbs in the body, it will lead to prameha.

Gestational Diabetes Mellitus is the metabolic disorder of pregnancy. It is a central and growing health problem in most parts of the world, with a global prevalence of between 2% and 6%.⁷ Gestational Diabetes mellitus is defined by the WHO as carbohydrate intolerance resulting in hyperglycaemia of variable severity with onset or first recognition during pregnancy.⁸

The entity is usually present late in the second and third trimesters.⁹

It is a metabolic disorder caused by a defect in insulin secretion or action, which leads to abnormalities in the metabolism of carbohydrates, lipids and protein¹⁰

Diabetes mellitus is a chronic illness that requires continuing medical care and ongoing patient self-management education and support to prevent acute complications and reduce long-term complications. In certain populations, such as Asians, particularly Indians, the prevalence of diabetes is high. Obesity and advanced gestational age are the other risk factors for gestational diabetes. Perinatal mortality and morbidity are high in untreated diabetic pregnancies¹¹

In the first half of pregnancy, there is increased insulin sensitivity; therefore, there is a tendency toward developing hypoglycaemia. On the other hand, the second half of pregnancy (especially after 24 weeks of gestation) is related to the development of insulin resistance. This insulin resistance is thought to be the cause of the pathogenesis of gestational diabetes.¹²

Prishniparni contains terpenoids and flavonoids, which have antidiabetic activity.

MATERIALS AND METHODS

Collection of drugs: The collection of Prishniparni was brought from a local pharmacy named Ekandanta Ayurvedic Medical Store. Devkule S.S from Savitribai Phule University did the authentication.

Drugs were prepared from Ayush Ayurveda L.L.P. pharmacy, Pune, with GMP, certified Pune, Maharashtra, India.

Standard operative procedure of Ghanavati

- 7 kg Prishniparni course powder cleaned and added with 112 litres of water.
- The mixture is boiled till $\frac{3}{4}$ water gets evaporated and reduced to 28 litres.
- The mixture was filtered, and 27.8 litres of kwath was obtained.
- The kwath is further boiled on mild heat to reduce to 1 litre, 700 g Prishniparni fine powder and 700 gm gum acacia (As excipient) added and mixed homogeneously. The mixture was further dried using a tray dryer at 55 °C.
- After drying, a 500 mg tablet was prepared using a rotary tableting machine.
- The prepared tablets are analysed for Total Hardness, pH, Moisture Content, Total Ash Value, Acid Insoluble ash, Water Soluble Extractive, Alcohol soluble Extractive, Loss of Drying, Friability Test, Disintegration time, and Average weight.

Dose: 500mg

Anupana: Warm Water

Duration: 15 Days

Sample size: This is an open clinical labelled study sample size of 20.

Prevalence Rate: 1.3%

Justification of dose and kala

Dose: According to Acharya sharangdhar, Matra of ghanavati is 1 karsh that is 10 gm. In Garbhini awastha, there is Agnimandya. So, we decided to give 1 gm/day matra for GDM.

Kala: 9 am – 9 pm (Kaphaj kala)

This is an open clinical labelled study.

Sample size: 20 patients.

Place: Bharati Ayurveda Hospital, OPD

Consent: written consent per guidelines in the local language is taken from each patient.

Selection Criteria

Inclusion criteria

- Garbhini Patients with raised DIPSI (>140 up to 200 mg%)

Exclusion criteria

- Garbhini Patients with raised DIPSI (above 200 mg%)
- Anaemic patients with Hb below 7 gm%
- Pregnancy-induced hypertension with GDM

Discontinue criteria

- Voluntary withdrawal by the patient.
- If the patient is not regular for follow-up, she shall be discontinued.
- Development of any side effect

Assessment Criteria

Patients were assessed by evaluating for signs and symptoms using subjective and objective parameters mentioned below,

Subjective criteria

- Polyuria (Prabhutavilmutrata)
- Nocturia (Naktamutrata)
- Polyphagia (Kshudhadhikya)
- Polydipsia (Pipasa)
- Excess sweating (Swedadhikya)

Objective criteria

- At 13 - 16 weeks: Haemogram, HIV, HbsAg, VDRL, Urine (routine and microscopic)
- At 24 - 28weeks: DIPSI (Diabetes in Pregnancy Societies of India).
- Repeated after 15 days.

RESULT

GDM is increasing day by day. In Indian populations, obesity during Pregnancy is observed in many patients. If the DIPSI is more than 200, then antihyperglycemic agents are the remedy. But if the sugar range is between 140 to 200, then most gynecologists prefer lifestyle modification. Sudden changes in dilatory habits and starting walking make a woman uncomfortable. In this study, the women were asked to avoid sugar intake except for one cup of tea. Thus, she was observed to be very comfortable with this regimen. The Ayurvedic herb, i.e. Prishniparni, is used in this study on the woman having raised sugar levels to 200.

The conclusion is drawn based on research work done from October 2019 - November 2021.

Prishniparni comes under the shothahra group. Its antidiabetic activity is well established in the animal study. In this study, antidiabetic activity, i.e., Antihyperglycemic activity, was observed in all patients as the blood sugar level became normal after treatment of 15 days. Prishniparni has laghu and sara guna, so the kleda gets reduced. Its ushna guna improved fat metabolism. The agnivaradhak action corrected agnimandya. Its tikta, katu rasa reduced the kleda. This broke the samprapti of GDM in the study group.

In this study, it is proved that prishniparni could be the choice of the herb in these cases.

Prishniparni proved effective in managing GDM if the BSL is less than 200. All patients well tolerated the herb. The side effects are not observed in this study.

DISCUSSION

Discussion is based on the observations done in a research project. In this study, 20 gravid subjects were observed who had raised DIPSI. DIPSI is the main criteria for the diagnosis of Gestational diabetes. The normal range of DIPSI is below 140 mg%. DIPSI Above 140 mg% and up to 200 mg% women included in this study. Discussion is done based on 20 women's detailed observations.

They are as follows:

- Age
- Height, weight, and BMI
- Prakruti
- Gestational weeks
- General Complaints
- Prabhutmutrata
- Naktamutrata
- Kshudha
- Pipasa
- Swedadhikya
- Family History
- Investigations-
- DIPSI - (Before and After Treatment)
- Blood Glucose Post Prandial
- Urine Glucose Post Prandial
- Hemogram

The observation is thoroughly discussed to conclude.

Age: The average age group in this study was 20 to 30 years of age. As per the available demographic study articles, the average marriage age in India is 20 to 30 years. A similar observation is noted in this study.

Height Weight BMI: Women having a combination of obesity with pregnancy are more prone to develop Gestational Diabetes Mellitus. Obesity is compared with the disease *sthaulya* mentioned in Ayurveda. *Sthaulya* is a disease of *apachit meda*. *Apachit meda* is the reason for abnormal *kleda*. Pregnancy is a phase where carbohydrate metabolism is altered. Thus, pregnant woman quickly lands into obesity. So, in 65% of women, *sthaulya*, i.e., obesity, is observed.

Prakruti: Dosha dominance in prakruti plays an important role. In a disease development of any disease. Thus, it is an observation that kapha dosha is either the principal or supportive dosha in the women who have raised DIPSI. Most women are of kapha domination or kapha *anubandhit prakruti*. Vitiating of Kapha is one of the causes of *kleda nirmiti*. *Kleda* is a significant reason for GDM.

Gestational Weeks: The administration of herb prishniparni is mentioned by Sushruta acharya in *garbhini paricharya* during 24 - 28 weeks. Suppose the *garbhini paricharya* advised by acharya is studied. In that case, one can find that other than dietary and routine herbal administration only during the 5th and 6th months, herbs are mentioned that have medicinal action. The sixth month is a duration when gestational diabetes could start. This relation

between 24-28 weeks and Gestational diabetes mellitus is well established.

So, in this study, it is proved that DIPSI gets reduced when Gestational Diabetes Mellitus is treated with prishniparni. The carbohydrate metabolism gets altered in 24-28 weeks of pregnancy. In this study also, the relation between altered carbohydrate metabolism is observed.

Prabhut-Mutrata: An increase in the frequency of micturition is a ubiquitous symptom of the 2nd trimester, but in this study, it is observed that the frequency is reduced after controlling the sugar levels. So, this can't be the sign of a typical 2nd trimester. This effect is due to *Sangrahi guna* of herb.

Nakta-Mutrata: *Naktamutra pravrutti* is a peculiar sign of increased blood sugar levels. This sign is observed in almost 65% of women. *Naktamutrapravrutti* is due to the *deepan* action of the herb. The *deepan* action is responsible for decreasing *kleda*.

Kshudha: *Agnimandya* is the most important cause of any disease. In this study, *agnimandya* is seen in all women. The *deepan* action of prishniparni is observed in all women. Thus, at the end of the study, all women presented with improved *agni*.

Pipasa: *Pipasa* is a crucial symptom of *prameha*. Almost 55% of subjects presented with a normal feeling of thirst after treatment. *Trushnagha* action of prishniparni reduced the increased sense of thirst in the study group.

Swedadhikya: *Swedadhikya* is a sign of *kapha pitta dushti*. *Swedadhikya* is due to abnormal *medopachan*. The *ushna guna* and *deepan* action of prishniparni reduced the *swedadhikya* in subjects.

Family History: Families have the same genetic factors, so family history is essential. DM is a genetically linked disorder. During pregnancy, the altered carbohydrate metabolism with genetic history can be one of the reasons for gestational diabetes mellitus.

Out of 20 women, only seven women have a family history of DM.

DIPSI -Blood Glucose Post Prandial: The increased blood sugar level becomes normal after the treatment. Prishniparni comes under the *shothahra* group. The antidiabetic activity of prishniparni was well established in an animal study. In this study, antidiabetic activity, i.e., antihyperglycemic activity, was observed in all patients as the BSL became normal after treatment of 15 days. Prishniparni has *laghu* and *sara guna*, so the *kleda* gets reduced. Its *ushna guna* improved fat metabolism. The *agnivardhak* action corrected *agnimandya*. Its *tikta, katu rasa* reduced the *kleda*. This broke the *samprapti* of GDM in the study group.

DIPSI- Urine Glucose Post Prandial: Pregnancy is an oxidative stress phase. The oxidative stress can activate the inflammatory process in the kidney, which results in the lapse of sugar through urine. Prishniparni is anti-inflammatory in action, i.e., *Shothagha*, in *prameha*, the kidney goes through inflammation, so leaking of glucose in glomerular filtration is observed. The *shotha* of *vrukka* got corrected, so the urine glucose level was decreased after treatment. Prishniparni balances *tridosha* through its *Laghu, Sara guna, Tikta, Amla, Madhur, katu rasa, ushna virya* and *madhur vipak*. Thus, the overall improvement in signs and symptoms of GDM was observed in the study group

CONCLUSION

According to this study, Prishniparni is effective in managing Gestational Diabetes Mellitus if blood sugar levels are less than 200. Side effects were not observed in this study.

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