Research Article

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A CLINICAL STUDY TO EVALUATE THE EFFECT OF TUVARAKA RASAYANA KALPA ON INCREASED BLOOD GLUCOSE LEVEL IN TYPE-2 DIABETES MELLITUS

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ABSTRACT

Background: Diabetes mellitus is one of the major health challenges of the current era, with sedentary lifestyle contributing significantly to its rising prevalence. The burden of diabetes is increasing day by day. In Ayurveda, Prameha, which can be correlated with diabetes mellitus, is described as a Yapya Vyadhi, whose line of management includes Shodhana, Shamana, and Rasayana. Tuvaraka Rasayana is one such Pramehahara Rasayana, mentioned in the classical texts as a Naimittika Rasayana. Objectives: To assess the effect of Tuvaraka Rasayana Kalpa on FBS and PPBS in Type-2 Diabetes mellitus. Methodology: This was a single-arm study conducted on 30 subjects who fulfilled the diagnostic and inclusion criteria and provided informed consent. All subjects received two capsules of Mishraka Sneha on an empty stomach for 4 days, followed by administration of 10 ml of Tuvaraka Taila on an empty stomach for the next 6 days. Thereafter, subjects were advised to follow their regular diet without any medication for 15 days. FBS and PPBS were assessed on the 0th, 5th, 11th, and 26th day. Results: The administration of Tuvaraka Rasayana Kalpa showed a significant reduction in FBS (p=0.001) and PPBS (p=0.027) by the end of intervention with sustained improvement observed up to the follow-up period. Conclusion: Tuvaraka Rasayana aids in the elimination of Vikrta Kleda along with Kapha and Meda, thereby facilitating a reduction in blood glucose levels within a short duration and supporting improved maintenance by preventing the further accumulation of Kleda.

Keywords: Vikrta Kleda, Naimittika Rasayana, Ubhayabhagashodhana, Caturthabhaktantarita

INTRODUCTION

Diseases that are associated with the way a person or group of people live are known as lifestyle diseases. They are primarily based on the day to day habits of people. Habits that detract people from activity and push them towards a sedentary routine can cause a number of health issues that can lead to chronic non-communicable diseases that can have near life-threatening consequences.[1] They include atherosclerosis; heart disease and stroke; obesity and type II diabetes; and smoking and alcohol-related diseases.[2]

The burden of diabetes is high and increasing globally, and in developing economies like India, mainly fuelled by the increasing prevalence of overweight/obesity and unhealthy lifestyles. A 2023 study by the Indian Council of Medical Research – India Diabetes (ICMR INDIAB) reported that 10.1 crore (101 million) people in India have diabetes.[3]

Diabetes is a progressive disorder that leads to serious complications, which are associated with increased costs to the family, community, and healthcare system. Chronic complications of diabetes include increased risk of vascular damage of both macrovascular (resulting in myocardial infarction, stroke, and lower extremity ischemia) and microvascular (resulting in diabetic retinopathy, nephropathy, and neuropathy) structures.[4]

Prameha which is akin with Diabetes Mellitus is caused mainly because of two reasons Bija Dushṭi (Hereditary) and Ahitahara Vihara (Improper diet and lifestyle).[5] Ahitahara Vihara mainly refers to indulgence in Kaphakara Ahara and Vihara, which in the present context can be correlated with a sedentary lifestyle.

In the management of Prameha, various regimens such as Dinacarya (Daily regimen), Ritucarya (Seasonal regimen), Pancakarma (Detoxification and Bio-purification therapy), and Rasayana (Rejuvination therapy) can be adopted. Among these, Rasayana therapy holds a significant place as it provides scope not only for the prevention of disease but also for the promotion of health and the management of existing illness. Classical texts mention that Tuvaraka Taila is highly effective in Kushtha (Skin disorders) and Prameha, where it acts as a Naimittika Rasayana.[6]

In the present fast-paced lifestyle, individuals often encounter difficulties in undergoing Shodhana (Purificatory therapies) therapies for extended durations, despite their proven efficacy in detoxifying the body. This underscores the need for alternative approaches that can effectively eliminate Dushita Doshas (Vitiated Dosha) and thereby aid in the regulation of blood glucose levels. Tuvaraka Rasayana has been described in the Ayurvedic classics as a highly effective formulation in the management of Prameha. Tuvaraka Taila induces Vamana (Emesis therapy) and Virecana (Purgation therapy), thereby facilitating the elimination of vitiated Doshas from the body. However, there exists a paucity of clinical research evaluating its

therapeutic potential. Here, we report the results of clinical study undertaken to assess the effect of Tuvaraka Rasayana Kalpa on elevated blood glucose levels in individuals with Type 2 Diabetes Mellitus.

MATERIALS AND METHODS

Study Design

The study was conducted on OPD basis in Sri Dharmasthala Manjunatheshwara College of Ayurveda, Hopsital and Research Center, Katpady, Udupi, Karnataka, India. Patients were enrolled between February 2025 and September 2025. The trial was completed in October 2025. The study was carried out as per ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. The Institutional Ethical Clearance Committee – Human of Sri Dharmasthala Manjunatheshwara College of Ayurveda, Hospital and Research Center Udupi approved the protocol. This trial is registered under Clinical Tril.gov, India (CTRI/2024/10/074655).

Objectives

Primary Objective: To assess the effect of Tuvaraka Rasayana Kalpa on Fasting Blood Glucose level in Type-2 Diabetes mellitus.

Secondary Objective: To assess the effect of Tuvaraka Rasayana Kalpa on Postprandial Blood Glucose level in Type-2 Diabetes mellitus.

Sample Size Estimation

The sample size was estimated using standard statistical principles applicable to single-arm interventional studies. A previous case series involving five patients showed improvement with Tuvaraka Rasayana. Based on these preliminary findings and assuming a medium effect size of 0.5, with a 5% level of significance and 80% power, the minimum required sample size was calculated to be 28 participants. Considering feasibility and potential dropouts, a total of 30 patients were enrolled in the study.

Diagnostic Criteria

- Fasting Plasma Glucose level ≥ 126 mg/dL
- Post Prandial Plasma Glucose level ≥ 200 mg/dL
- HbA1C > 6.5%

In asymptomatic patients 2 findings are required for the diagnosis of Type-2 Diabetes Mellitus.
In symptomatic patients 1 finding is required for the diagnosis of Type-2 Diabetes Mellitus.[7]

Inclusion Criteria

- HbA1C > 6.5%
- Fasting Plasma Glucose level ≥ 126 mg/dL (7.0mmol/L)
- Post Prandial Plasma Glucose level ≥ 200 mg/dL (11.1 mmol/L)
- Age between 30-60 years

Exclusion Criteria

- Type 1 DM
- Under anti-hyperglycemic drugs
- Diabetic Neuropathy, Diabetic Nephropathy, Diabetic Retinopathy, Ischemic heart disease, Gestational Diabetes

Assessment

FBS and PPBS were reviewed on 0th, 5th, 11th and 26th day

Intervention

All participants selected for the study were subjected for Koṣṭha Shuddhi (Purification of the alimentary canal) with Mishraka Sneha. 2 capsules of Mishraka Sneha was given on empty stomach at early morning for 4 days.

After Koshta Shodhana, from 5th day subjects were administered 10ml of Tuvaraka Taila orally on empty stomach at early morning for 6 days. During this period participants were instructed to consume only normal drinking water and to avoid foods possessing Ushna Virya (Hot in Potency) such as Kulattha (Horsegram), Dadi (Curds).

After completion of Tuvaraka Taila administration participants were advised to follow regular diet without medication for next 15 days.

Statistical Analysis

Statistical analysis was performed using IBM SPSS software (version 31.0.1.0; IBM Corp., Armonk, NY, USA). Descriptive statistics were used to summarize the data. FBS and PPBS were compared using the paired t-test.

RESULTS

Baseline Characteristics

A total of 38 patients were initially screened. All patients underwent FBS, PPBS, and HbA1c assessments during their OPD visit. Of these, 30 patients who fulfilled the diagnostic and inclusion criteria and gave voluntary, written, informed consent, were enrolled in the study. The demographic and baseline characteristics of the study participants are presented in Table 1.

Range of Koshṭha Shuddhi

Range of Koshtha Shuddhi observed during the intervention period is presented in Table 2. Most participants (33.3%) achieved Koshtha Shuddhi score between 3.5-4.25, indicating a satisfactory Koshtha Shodhana following administration of Mishraka Sneha.

Observation of Vamana Vega

Daily observation of Vamana Vega during Tuvaraka Taila administration is presented in Table 3. Mild Vamana response was observed in the initial two days, with gradual reduction by day 4 and complete absence thereafter.

Observation of Virecana Vega

Daily Virecana Vega scores are shown in Table 4. A moderate Virecana response was consistently observed from day 1 to day 6, with mean values ranging between 1.77 and 2.03 per day.

Changes in Fasting and Postprandial Blood Glucose Level

Changes in FBS and PPBS levels during and after the intervention are illustrated in Figures 1 and 2. A progressive decline was observed in both parameters from baseline to the post-treatment and follow up periods. Statistical analysis using the paired t-test revealed a significant reduction in FBS from baseline by day 5 ($p<0.05$) and highly significant reduction by day 11 and day 26 ($p<0.001$). Similarly, PPBS values showed a downward trend throughout the treatment period, with significant reduction observed on day 11 and day 26 (<0.05). These findings indicate a consistent improvement in glycaemic control following the administration of Tuvaraka Rasayana Kalpa.

Adverse Events

No adverse events were noted during the treatment course.

Table 1: Demographic and Baseline Characteristics of the Study Participants

Parameter	Category	n (%)
Age Group (years)	36-40	4 (13.3)
	41-45	7 (23.3)
	46-50	5 (16.7)
	51-55	7 (23.3)
	56-60	7 (23.3)
Gender	Male	16 (53.3)
	Female	14 (46.7)
Socioeconomic status	Lower	5 (16.7)
	Middle	21 (70.0)
	Upper	4 (13.3)
BMI (kg/m^2)	Underweight (<18.5)	1 (3.3)
	Normal (18.5-24.9)	18 (60.0)
	Overweight (25-29.9)	11 (36.7)
Koshtha Type	Mrudu	4 (13.3)
	Madhyama	19 (63.3)
	Krura	7 (23.3)
Agni	Madhyama	16 (53.3)
	Tikshna	7 (23.3)
	Vishama	7 (23.3)
Dushita Dosha	Kapha	11(36.7)
	Kaphapitta	12 (40.0)
	Kaphavata	6 (20.0)
	Vatapittakapha	1 (3.3)
FBS (mg/dl)	126-160	13 943.3)
	161-200	6 (20.0)
	201-240	5 (16.7)
	241-280	3 (10.0)
	281-320	2 (6.7)
	321-360	1 (3.3)
PPBS (mg/dl)	200-250	17 (56.7)
	251-300	6 (20.0)
	301-350	3 (10.0)
	351-400	1 (3.3)
	>400	3 (10.0)
HbA1c (%)	6.5-7.0	8 (26.7)
	7.1-8.0	8 (26.7)
	8.1-9.0	6 (20.0)
	9.1-10.0	3 (10.0)
	>10.1	5 (16.7)

Table 2: Range of Koshṭha Shuddhi

Koshtha Shuddhi Range	No of Subjects	Percentage
0.5-1.24	1	3.3
1.25-1.99	4	13.3
2.00-2.74	6	20
2.75-3.49	9	30
3.50-4.25	10	33.3

Table 3: Observation of Vamana Vega

Day	No of Subjects	Minimum	Maximum	Mean
1	30	0	1	0.10
2	30	0	2	0.10
3	30	0	1	0.03
4	30	0	0	0.00
5	30	0	0	0.00
6	30	0	0	0.00

Table 4: Observation of Virecana Vega

Day	No of Subjects	Minimum	Maximum	Mean
1	30	0	5	1.90
2	30	0	5	1.83
3	30	0	5	2.03
4	30	0	5	1.80
5	30	0	5	1.83
6	30	0	5	1.77

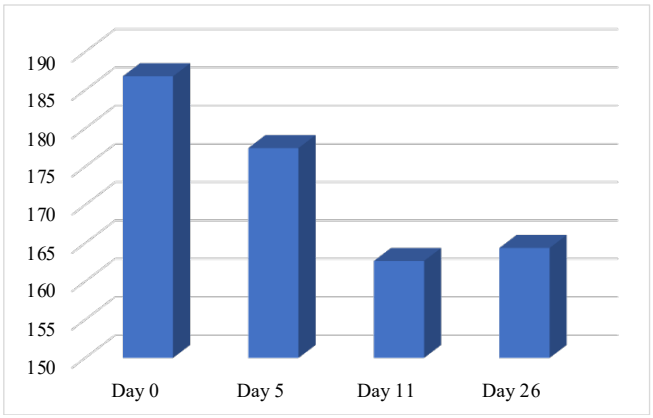

Figure 1: Changes in Fasting Blood Glucose level during and after intervention

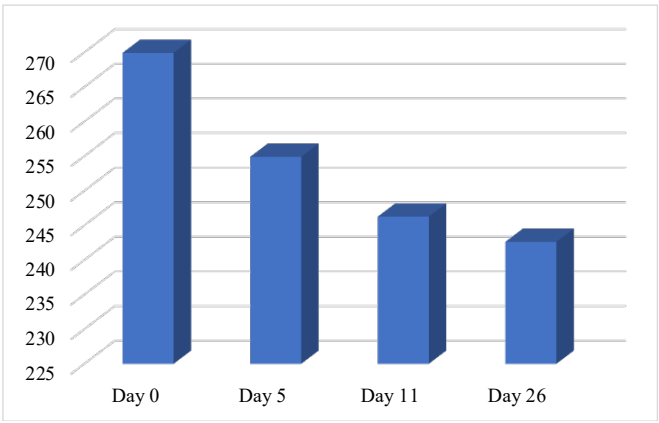

Figure 2: Changes in Postprandial Blood Glucose level during and after intervention

DISCUSSION

Diabetes mellitus remains one of the most challenging, metabolic disorders of modern times, reflecting the cumulative impact of sedentary lifestyle, altered diet, and chronic psychological stress. Its prevalence has increased alarmingly in India, affecting millions across all socioeconomic backgrounds and transforming into a major public health concern. Although currently available oral hypoglycaemic agents and insulin provide short-term glycaemic control, their limitations such as progressive drug resistance, hypoglycaemic risk, weight gain, and dependence indicate the need for the exploration of safer, more holistic alternatives. Ayurveda offers valuable insights into this area through its concept of Rasayana therapy, which not only aids in disease management but also enhances the functional efficiency of body systems, thus preventing further progression and complications. Among many Rasayana explained Tuvaraka Rasayana has been mentioned to be beneficial in Kushtha and Prameha.[8] Previous experimental and case series have shown that Tuvaraka Taila exhibits hypoglycaemic activity, reducing elevated blood glucose levels.[9,10]The present study was therefore designed to scientifically evaluate the effect of Tuvaraka Rasayana Kalpa on raised blood glucose levels in newly diagnosed cases of Type-2 Diabetes mellitus.

30 newly diagnosed subjects were enrolled for the study, considering a small sample size to be appropriate to facilitate ease of observation, better monitoring and to ensure close follow-up of each patient throughout the study period. Including only newly diagnosed or recently diagnosed patients but not under any hypoglycaemic drugs ensured that the changes in glycaemic indices could be attributed solely to the intervention without interference from conventional hypoglycaemic drugs. The diagnostic criteria adopted FBS ≥ 126 mg/dL, PPBS ≥ 200 mg/dL and HbA1c > 6.5% followed standard diagnostic guidelines, providing uniform baseline for assessment.[7]

The demographic distribution of the study group reflected the epidemiological pattern of Type-2 Diabetes mellitus, with majority between 41 and 60 years of age. Middle age is a known risk period due to progressive insulin resistance, accumulation of visceral fat, sedentary lifestyle and age-related metabolic decline. Since all the patients were newly diagnosed or recently diagnosed but not yet under medication, many were asymptomatic and were diagnosed incidentally during routine blood investigation, while a few presented with mild symptoms such as increased thirst, burning sensation in palms and soles, fatigue, or unexplained weight loss. This also highlights the importance of early screening for diabetes in individuals above 35 years of age to ensure timely diagnosis and management.

The predominance of subjects following a mixed diet, might have influenced the disease profile. Most of the subjects were from in and around Udupi. Consumption of Matsya mamsa (Fish) and Kukkuta mamsa (Chicken meat) is common in this region. Kukkuta Mamsa has Guru (Heavy), Snigdha (Unctuous) Guna (Quality) and is Shleshma Vardhaka (Increases Kapha Dosha), while Matsya Mamsa has Madhura Rasa, Guru, Snigdha Guna, is Parama Kaphakara (Aggravates Kapha Dosha excessively) and Bahu Doshakara.[11-13] Further, many Dhnayas (Cereals and Pulses) currently available in the market are Nava (Newly harvested), which possess Madhura Rasa, Guru, Snigdha Guna and are Kaphakara in nature. Such Madhura Kaphakara Ahara are classical Nidana(Etiological factors) for Prameha and are

responsible for aggravation of Kapha, Meda and Kleda due to Samanya Guna.

The baseline BMI distribution showed that 60% of participants were within the normal range, while 36.7% were overweight and 3.3% were underweight. The high proportion of overweight individuals highlights the established role of increased body weight as a major risk factor for Type 2 Diabetes mellitus.[14] Individuals with Sthula Sharira (Obesity) and those consuming Guru, Snigdha Ahara are more prone to Kapha and Meda Dushti, which constitute the principal Dosha and Dushya in Prameha. In Ayurvedic literature there is well established relation between Atisthaulya and Prameha. Prameha is one of the complications of Atisthaulya which justifies the observation.[15] Most participants exhibited Madhyama Vyayama Shakti, reflecting moderate exercise tolerance. Limited physical activity, recognised in Ayurveda as Avyayama and Eka-Sthana-Asana-Rati, which are listed among Nidana for Prameha and is directly comparable to sedentary lifestyle induced insulin resistance in modern physiology.

From the biomedical viewpoint, hyperglycaemia in type 2 diabetes results primarily from a combination of insulin resistance and β-cell dysfunction. Insulin resistance in liver, muscle and adipose tissue raises fasting and postprandial glucose levels, and progressive β-cell failure causes worsening and persistence of hyperglycaemia.[16] In the Ayurvedic frame, Kleda is considered a fundamental Duṣhya that becomes aggravated in Prameha. Kleda when in excess mixes with the Shareera Udaka Bhavas like Mutra (Urine) and Rudhira (Blood). Continuous consumption of Madhura Pradhana Aahara leads to accumulation of Kleda which when mixed with the Shareera Udaka bhavas increases their Madhurata and manifests clinically as Shatpada Pipilikabhisca Shareera Mutra Abhisaranam (Insects and ants are attracted towards the body and urine of the effected person), the Purvarupa of Prameha. In modern diagnostic terms, these early subtle manifestations correspond to detectable hyperglycaemia and glycosuria, enabling objective assessment through blood and urine investigations.

The treatment protocol followed the fundamental principle of Koshtha Shodhana prior to Rasayana administration. Classical texts emphasize that the therapeutic potential of Rasayana is best realised only in a purified body, just like a clean cloth that better absorbs dye.[17] Considering the outpatient setting and the need for Mrudu Shodhana, Mishraka Sneha Capsules were used for Koshtha Shuddhi. Mishraka Sneha contains Trivrut, Triphala, Danti, Pippali, Drakṣha, Eranda Taila, and Kshira, all of which possess Virechaka guṇa, thus facilitating effective Koṣtha Shodhana. Acharya Vagbhata has recommended it in Gulma describing it as Parama Sramsaka.[18] In current study Mishraka Sneha from a GMP certified company was administered in a dose of two capsules per day for four days, following manufacturers guidelines and supported by previous case series.[10] This Mrudu Shodhana made the body more receptive to subsequent Rasayana therapy.

Following Koshtha Shodhana 10ml of Tuvaraka Taila was given for six consecutive mornings on empty stomach. Classical references mention Panitala Matra (12ml) dose, yet prior clinical experience demonstrated that such quantities could produce pronounced Vamana and Virecana with dehydration. The slightly reduced dose achieved desired Ubhayabhaga Shodhana while maintaining safety. The total dose of 60ml over six days matched the classical cumulative dosage recommendations.[19,20]

Tuvaraka Taila, being endowed with Uṣhna and Tikshṇa Guna, facilitates Dosha Sraavana (Expulsion of aggravated Dosha). By virtue of its Prabhava, these Doshas are expelled both through Urdhva and Adho Bhaga. Thus, the Ubhayatobhaga Shodhana quality of Tuvaraka Taila manifested in the form of both Vamana and Virecana in the study participants. The absence of Vamana Vega after day 4 may be attributed to the lower dose, as the previous case series using the dosage of 12ml produced 1-2 Vamana Vega, indicating a dose dependent response. The selected dose thus achieved moderate Shodhana without causing dehydration or discomfort.

Mrudu Koshtha Shodhana with Mishraka Sneha aids elimination of Kleda through Virecana thereby contributing to lowered blood glucose. In Prameha, Vikruta Kleda arising from Vikruta Kapha and Meda is assossiated with Rudhira and Mutra. Tuvaraka Taila produced Ubhayatobhaga Shodhana, expelling Kapha and Kleda through Vamana and Meda and Kleda through Virecana thus causing Samprapti Vighatana (Breaking the pathogenesis). The depletion in Kledamsha leads to corresponding reduction in blood glucose levels. The Ushna, Tikshna Guna along with Kashaya and Tikta Rasa of Tuvaraka are antagonist to Kleda, Kapha and Meda. These impart Kleda Shoshana action thereby reducing Vikruta Kleda in Rudhira leading to corresponding reduction in blood glucose levels. By normalizing Kapha and Meda and preventing further Kleda accumulation, Tuvaraka Rasayana Kalpa sustains its effect beyond treatment. During follow up, patients maintained stable blood glucose without rebound hyperglycaemia, demonstrating both corrective and preventive action on metabolic imbalance.

From a contemporary pharmacological perspective, the amphiphilic antioxidant molecules present in Tuvaraka help in mitigating oxidative stress-mediated β-cell dysfunction, thereby supporting sustained endogenous insulin secretion.[9] Bioactive constituents such as hydnocarpin, isohydnocarpin, and luteolin, exhibit α-glucosidase inhibitory activity, leading to delayed intestinal carbohydrate breakdown and a reduction in postprandial hyperglycaemia.[21] Additionally, hydnocarpin has been observed to modulate carbohydrate-metabolizing enzyme pathways, and luteolin enhances peripheral glucose uptake via insulin signalling modulation.[22]

CONCLUSION

In conclusion the present clinical study provides evidence that Tuvaraka Rasayana Kalpa can effectively reduce raised blood glucose levels and improve metabolic equilibrium in patients with Type 2 Diabetes Mellitus. By integrating Mrudu Shodhana and Rasayana, the therapy achieves both elimination of Vikruta Dosha, Dushya and rejuvenation of physiological function.

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