



ORIGINAL RESEARCH PAPER

Ayurveda

HYPOGLYCEMIC EFFECT OF KADARYADI KWATHA YOGA IN TYPE 2 DIABETES MELLITUS

KEY WORDS: Type 2 Diabetes mellitus, Kaidaryadi kwatha yoga, FBS, PPBS, HbA1c

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ABSTRACT
 Type 2 diabetes mellitus, previously referred to as 'Non insulin dependent' or 'maturity onset diabetes' is a heterogenous condition characterised by variable defects in both insulin secretion and insulin action. In conjunction with genetic susceptibility, type 2 diabetes mellitus is brought on by environmental and behavioural factors such as sedentary lifestyle and obesity. Due to the resultant microvascular and macrovascular complications, it possesses great economic and functional burden. This study was undertaken to clinically evaluate the hypoglycemic effect of the well known Ayurvedic formulation *Kaidaryadi kwatha yoga* in Type 2 Diabetes mellitus. The study was conducted pre and post without control group in 30 patients. FBS, PPBS and HbA1c was done before and after treatment. Statistical analysis revealed significant reduction in FBS, PPBS and HbA1c levels with a p value <0.001. Thus the formulation was found to be effective in reducing the glycaemic levels and symptoms of Type 2 Diabetes mellitus.

INTRODUCTION

With tremendous development and globalisation over the past few decades, there has been a shift in disease trend towards non communicable diseases (NCDs). NCDs are chronic diseases which are born out of combination of genetic, physiological, environmental and behavioural factors, the onset of which is insidious and once encountered do not lend themselves easy to cure. Cardiovascular diseases account for most NCD deaths ie, 17.7 million people annually, followed by cancers (8.8 million), respiratory diseases (3.9 million), and diabetes (1.6 million).¹ Metabolic risk factors including obesity and hyperglycemia associated with type 2 diabetes mellitus contribute to key metabolic changes that increase the risk of NCDs especially cardiovascular disorders along with hypertension and dyslipidemia. Type 2 diabetes mellitus, is a chronic metabolic disorder which consists of an array of dysfunctions characterized by hyperglycemia resulting from the combination of resistance to insulin action and inadequate insulin secretion. Thus it becomes one among the four major non communicable diseases and acts as a potential risk factor to the development of other NCDs. The prevalence of Type 2 Diabetes mellitus (DM) has been increasing steadily all over the world. India is currently experiencing an epidemic of type 2 diabetes mellitus and is often referred to as the diabetes capital of the world. According to WHO 2015 data, India had 69.2 million people living with diabetes (8.7%)². People living with type 2 DM are more vulnerable to various forms of both short and long term complications, which often lead to their premature death. Management of type 2 DM includes detecting, screening and treating the disease at the earliest and concentrates on keeping blood sugar levels as close to normal as possible which can be done with close dietary management, exercise, and use of appropriate medications.

Type 2 Diabetes mellitus may be included under the broad spectrum of prameha described in Ayurveda and can be nearly correlated with madhumeha, one of its types. It seems to evolve from a wide range of metabolic derangements starting with the vitiation of kapha. The pathogenic process continues with the involvement of dushyas especially medas and an increase in sareera kleda, which gets expelled through mutra. The other doshas get involved in further stages of the disease, finally culminating in a vatika stage where there occurs dhathu kshaya or deterioration of body tissues.

Though there are effective drugs working on specific glucose regulating mechanisms, according to prospective cross-sectional studies, insufficient glycaemic control remains the reason for changing therapy in 70% of the patients³. Also, limiting of Diabetes mellitus without complications in long term and maintenance of euglycemia without causing hypoglycemia is still a challenge to the medical system⁴. Ayurvedic anti-diabetic medications show significant effect in lowering the blood sugar levels with minimal side effects. These drugs also improve general debility along with providing antioxidant property⁵.

This study aims at re validation of one such formulation- *Kaidaryadi kwatha*, in the management of type 2 diabetes mellitus.

MATERIALS AND METHODS

Study drug details: The study formulation is mentioned in the 'Mahodara Chikitsa' adhayaya of 'Chikitsa Manjari'⁶ and contains 4 drugs – Sunti (Zingiber officinale - dried rhizome), Kaidarya (Murraya koenigii - leaves), Patola (Trichosanthes cucumerina – root) and Pathya (Terminalia chebula – fruit) along with adjuvant (anupana) drugs, Saindhava (rock salt) and Pippali (Piper longum – fruit). Of these, the hypoglycemic effects of kaidarya, patola and pathya in animals are proven scientifically⁷⁻¹². Also all the drugs showed antidyslipidemic effects in experimental studies, which is significant, since most of the diabetic patients also have dyslipidemia.

Method of preparation: Certified samples of drugs were procured. Sunti, kaidarya, patola and pathya were taken in the ratio of 1:3:4:4. They were cleaned, dried, powdered separately, mixed thoroughly and given to patients in airtight packets each containing 48 g medicine. Anupana dravyas saindhava and pippali were taken in equal quantities, finely powdered separately, thoroughly mixed and dispensed in packets of 1.5g each, along with each packet of kwatha choorna.

Study Design: Interventional study – Pre & Post test.
Study setting: Outpatient and Inpatient Department of Kayachikitsa, Govt. Ayurveda College Hospital, Thiruvananthapuram, Kerala.

Inclusion criteria: 1. Patients of both sexes in the age group of 30-60 years.

Need and significance of the study

2. Newly identified patients with FBS level from 126 mg/dl-200mg/dl or PPBS level from 200 mg/dl-250mg/dl.
3. Newly identified patients with HbA1c level below 9 %.

Exclusion Criteria:

1. Diagnosed cases of diabetes with established features of nephropathy and retinopathy or other systemic disorders.
2. Pregnant or lactating women.
3. Patients on steroids, oral contraceptives and estrogen tab.

Sample size: 30 cases, analytically calculated using the formula,

$$N = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (Z_{1-\alpha/2})^2}{\Delta^2}$$

Sampling Technique: Consecutive sampling.

Data collection: By detailed clinical research proforma and laboratory investigations including FBS, PPBS, HbA1c, liver function tests, renal function tests and lipid profile.

Procedure: Patients both male and female in the age group of 30-60 from the study setting were selected for the study. They were subjected to detailed clinical examination and investigations including fasting blood sugar (FBS), 2h Post prandial blood sugar (PPBS), HbA1c, LFT, RFT and lipid profile were done. Informed consent was obtained from the patients satisfying the inclusion criteria. The study was conducted in a single group. The study drug was given to the patient for 90 days in airtight packets each containing 48 g coarse powder with date of administration labeled on packets. The patient was advised to prepare kwatha by adding 768ml of water to 48 g coarse powder, boiled and reduced to 96ml in a mud pot without lid. The anupana dravyas saindhava and pippali were powdered and dispensed in packets of 1.5 g each, along with each packet of kwatha choorna. The patient was advised to take 48ml of luke warm kwatha twice daily before food in empty stomach along with anupana (1.5 g each of saindhava and pippali). 15 such packets were given to them in each visit with an interval of 15 days. The patient was further evaluated on the 31st, 61st and 91st day on the basis of laboratory findings and signs and symptoms. The result obtained was statistically analyzed and concluded.

Outcome Variables: Changes in FBS, PPBS and HbA1c

Statistical analysis: The collected data was subjected to statistical analysis using appropriate statistical techniques. Pre test- post test comparison of quantitative variables was assessed by paired t test. A 'p' value of 0.05 was taken as level of significance.

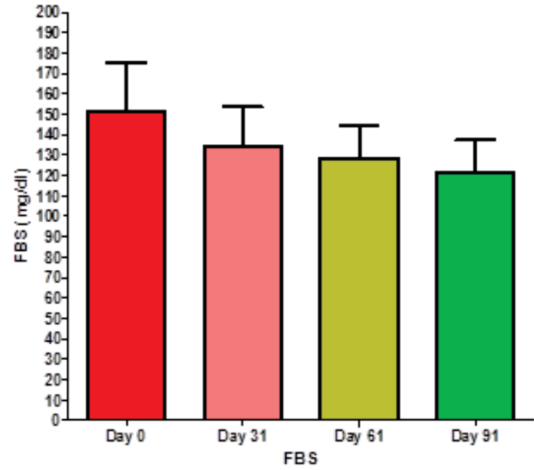
Ethical consideration: The research drug is being traditionally practiced for a long period. No known side effects were reported till now. Before conducting the study, clearance from the Institutional ethical committee and informed consent from the patient was obtained.

RESULTS: The results obtained were represented as follows:

a. Data related to FBS

Table 1: Effectiveness of treatment on FBS

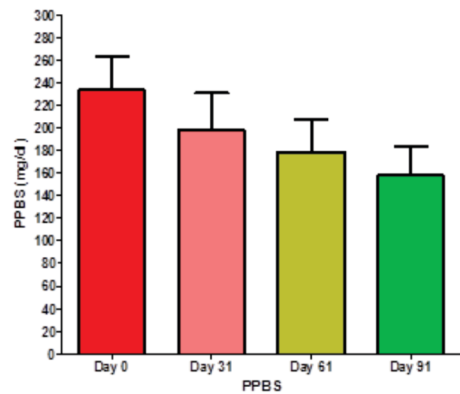
| | N | FBS | | Paired comparison | Paired difference | | Paired t test | |
|--------|----|-------|------|-------------------|-------------------|------|---------------|--------|
| | | Mean | sd | | Mean | sd | t | p |
| Day 0 | 30 | 151.7 | 23.3 | | | | | |
| Day 31 | 30 | 134.3 | 19.3 | Day 0 vs Day 31 | 19.5 | 17.4 | 4.891 | <0.001 |
| Day 61 | 30 | 128.6 | 16.2 | Day 0 vs Day 61 | 19.9 | 23.1 | 6.357 | <0.001 |
| Day 91 | 30 | 121.2 | 16.3 | Day 0 vs Day 91 | 19.6 | 30.5 | 8.533 | <0.001 |



b. Data related to PPBS

Table 2: Effectiveness of treatment on PPBS

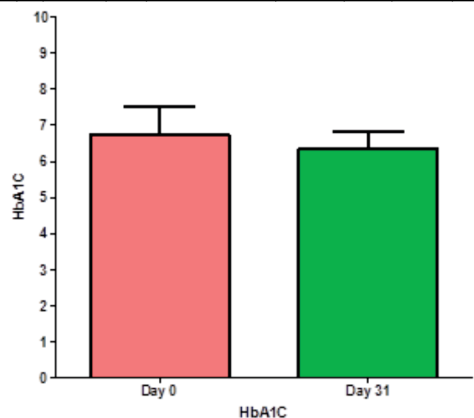
| | N | PPBS | | Paired comparison | Paired difference | | Paired t test | |
|--------|----|-------|------|-------------------|-------------------|------|---------------|--------|
| | | Mean | sd | | Mean | sd | t | p |
| Day 0 | 30 | 233.8 | 29.7 | | | | | |
| Day 31 | 30 | 198.5 | 32.4 | Day 0 vs Day 31 | 37.8 | 35.3 | 5.111 | <0.001 |
| Day 61 | 30 | 178.8 | 28.3 | Day 0 vs Day 61 | 41.3 | 55.0 | 7.296 | <0.001 |
| Day 91 | 30 | 167.8 | 25.9 | Day 0 vs Day 91 | 35.1 | 76.0 | 11.840 | <0.001 |



c. Data related to HbA1c

Table 3: Effectiveness of treatment on HbA1c

| | N | HbA1c | | Paired comparison | Paired difference | | Paired t test | |
|--------|----|-------|-----|-------------------|-------------------|-----|---------------|--------|
| | | Mean | sd | | Mean | sd | t | p |
| Day 0 | 30 | 6.7 | 0.8 | Day 0 vs Day | 0.5 | 0.4 | 4.690 | <0.001 |
| Day 31 | 30 | 6.3 | 0.5 | 31 | | | | |



The data on clinical parameters such as polyuria, polydipsia, polyphagia, fatigue, weight loss, arthralgia, altered sensations, excessive sweating, dryness of mouth, itching and blurring of vision were collected from the patients before and

after the intervention and calculated the frequency and percentage of respondents in grade 0,1,2,3 which represents absent, mild, moderate, severe respectively before treatment and after treatment. There was subjective improvement in all the symptoms corresponding to the improvement in glycemic level.

DISCUSSION

Type 2 diabetes mellitus, a chronic metabolic disorder is now taking its place as one of the main threats to human health in the 21st century. The etiopathogenesis, clinical features and management of Diabetes mellitus have been described in detail in Ayurvedic samhithas under the spectrum of prameha. The drugs useful in treating prameha should have kapha, medohara property to interrupt the samprapthi, deepana-pachana properties to correct the agni and thus the deranged metabolism and rasayana property to prevent dhathu nasa or complications.

The present study is meant to evaluate “*The hypoglycemic effect of Kaidaryadi kwatha yoga in Type 2 Diabetes mellitus*”. The study emphasizes the effectiveness by evaluating the changes in FBS, PPBS and HbA1c. The formulation as a whole possess katu, tiktha rasa; laghu guna; ushna veerya; katu vipaka and kapha pitta samanatwa. It is having deepana, pachana, anulomana, kledahara and rasayana properties. Thus, it becomes ideal in the kapha pitta stage of samprapthi, where there is kleda vriddhi.

The drug was well tolerated by majority of the patients. But adverse drug reactions such as gastric irritability, increased bowel frequency and loose bowels were observed in 5 out of 30 patients (16.7%) which is assumed to be due to the anupana dravyas saindhava and pippali, which can be avoided in such patients if needed.

The drug showed statistically significant reduction in FBS, PPBS and HbA1c ($p < .001$) and improvement in clinical symptoms in concordance with the improvement in glycemic level.

CONCLUSION

In nut shell, it can be concluded that the study drug *Kaidaryadi kwatha yoga* is effective in lowering the fasting and post prandial blood glucose levels. It can be used in patients with freshly detected type 2 diabetes mellitus with kapha predominant symptoms.

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