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RESEARCH ARTICLE

Efficacy of Polyherbal Formulation (*Phalatrikadi Vati*) in the Management of Type 2 Diabetes Mellitus through Metabolic Correction – A Clinical Study

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Abstract

Background: Diabetes mellitus is a prevalent metabolic disorder worldwide; its incidents have grown notably in recent years. Over the last 50 years, lifestyle changes have led to a dramatic increase in the prevalence of type 2 diabetes around the world. India has been projected as the diabetic capital of the world. Diabetes and its complications pose a major threat to future public health resources throughout the world and are the major cause of blindness, kidney failure, heart attacks, stroke, and lower limb amputation. In the southern part of India, the mortality rate due to diabetes mellitus is in fifth rank amongst the ten vital causes of death. Despite recent advances in knowledge, preventing and controlling diabetes remain a major challenge. So the present study has focused on the disease pathogenesis and its regulation through Polyherbal formulation ***(****Phalatrikadi Vati*). **Objectives:** To determine the efficacy of Polyherbal formulation in reducing the subjective complaints in Type 2 Diabetes Mellitus by metabolic corrections and thereby controlling the blood glucose level in the body. **Methods**: A single arm open labeled trial with 1 month in duration. Participants: 25 patients of Diabetes Mellitus Type 2 with diagnosed, high fasting blood sugar and postprandial blood sugar levels. 500mg tablet was given in twice a day after food. **Results:** A total of 30 patients enrolled in the study and 25 patients completed the treatment**.** Significant relief of 68% in polyuria, 56% in urine turbidity, 84% in polyphagia, and 76% in polydipsia seen. There was a highly significant reduction in FBS with a mean difference of 31.84 mg and PPBS with a mean difference of 63.92 mg. **Conclusion:** The polyherbal formulation is a safe intervention and can be expected to reduce the symptoms of Type 2 Diabetes Mellitus and blood sugar levels. Future studies with larger sample sizes, longer duration of intervention and follow up needed for more accurate and reliable results.

Keywords: *Ayurveda*, Diabetes Mellitus, *Phalatrikadi Vati*, Polyherbal Formulation

1. Introduction

Diabetes mellitus is a metabolic endocrinal ailment. The significant increase in ubiquity is expected to occur in Asia and Africa, where most patients will likely be found by 2030. In 2020, according to the International Diabetes Federation (IDF), 463 million people have diabetes in the world and 88 million people in the southeast Asia region. Of 88 million people, 77 million belong to India. The ubiquity of diabetes in the population is 8.9%, according to the IDF[1]. The lifestyle change of the past 5 decades has led substantial increase in the ubiquity of type 2 diabetes in virtually every society around the world. Vital parameters in bringing these abrupt changes are Depletion in physical activities shoot up in dietary intake, westernization of diet, and aging of the population[2].

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Diabetes is a syndrome characterized by disordered metabolism and abnormally high blood sugar resulting from insufficient levels of the hormone insulin[3]. Diabetes Mellitus is anticipated as a major health issue due to its grave complications, especially at the end stage of renal disease, Ischemic Heart Disease (IHD), gangrene of the lower limbs and blindness in the adults[4].

Prameha is a disease, which indicates an increased frequency or quantity of urine passed out of the body[5]. Type 2 DM has been classified under the subtype of *Vataja Prameha* as per Ayurveda[6]. Type 2 DM is the clinical entity in which the patient voids the urine having concordance with Madhu (honey-like colour) and the body acquires sweetness called Diabetes Mellitus[7]. In Type 2 DM, *Vata Dosha* (body humours) may be provoked directly either by its causative factors, interruption by *Kapha* and *Pitta* to its path, or by continuous depletion of body tissues[8]. Ayurveda believes that all disorders in the body are due to metabolic imbalance, DM is not an exception to this[9]. The present study is aimed at correcting metabolism and thereby controlling the metabolism of glucose in the body.

The characteristic features are immoderate urine production (polyuria) due to high blood glucose levels, immoderate thirst (polydipsia), and attempting to remunerate for increased urination. Here the present study intended to turn down the associated signs and symptoms of the disease and prevent the further advancement of the disease leading to complications prevention by regularizing the blood glucose level with the help of palliative medicine. The combination of this formulation the drugs like *Triphala*, *Haridra*, etc., which are proven hypoglycemic by experimental studies. The polyherbal formulation contains seven herbal drugs, these are said to be *Kaphagna*, *Mehagna*, *Medogna*, and *Mootasanghraneeya*. Thus the selected formulation is the drug of choice for the clinical study. Hence the study was intended to evaluate the efficacy of polyherbal formulation in Type 2 DM and to evaluate its efficacy of hypoglycemic activity.

2. Methodology

The study was a simple random sampling method. The patients attending the OPD of Department of Medicine Shri DGM AMC Gadag, Karnataka, India with a history of Type 2 DM and fulfilling the criteria of selection were registered. The detailed history was filled up in the specially prepared pro forma. A total of 25 patients, fulfilling the criteria of diagnosis of Type 2 DM were selected in the present study. The study was started after receiving IEC clearance from the institute. As the study was conducted from 2008-2010, when CTRI registration was not mandatory, CTRI registration cannot be done now, as retrospective registration of clinical study is not available on the website. Participants were advised to follow the routine and strict diet and exercises had not been advised to participants.

2.1 Inclusion Criteria

Patients suffering from symptoms of Type 2 DM (Type 2 Diabetes Mellitus) from the age group of 25-65 years of either gender, already diagnosed, chronicity of 4 months-10 years. Patients are willing to give written consent. Fasting blood sugar range between 120 mg/dl–200 mg/dl and postprandial blood sugar ranges between 200 mg/dl–350 mg/dl were selected.

2.2 Exclusion Criteria

Patients suffering from complications of diabetes Mellitus and suffering uncontrolled hypertension, congestive cardiac failure, type 1 diabetes mellitus, juvenile diabetes, malnutritional, and gestational diabetes mellitus were excluded from this study.

2.3 Assessment Criteria

Subjective criteria include polyuria, turbid urine, polyphagia, polydipsia, burning sensation of hands and foot, excessive sweating, and general debility. Subjective parameters are assessed by giving grades. An objective criterion includes FBS, PPBS, and urine sugar.

2.4 Subjective Parameters

- Polyuria

  Grade 0: 1000 ml – 1500 ml/24hrs
  Grade 1: >1500 ml/24hrs
  Grade 2: >2000 ml/24hrs
  Grade 3: >3000 ml/24hrs

- Turbid Urine

  Grade 0: Translucent fluid
  Grade 1: Unclear with slight turbidity
  Grade 2: Turbidity is present but newsprint can be read
  Grade 3: More turbidity cannot read newsprint

- Polyphagia

  Grade 0: Normal
  Grade 1: Minimal but tolerable
  Grade 2: Medium increase but tolerable
  Grade 3: Extremely increase but not tolerable

- Polydipsia

  Grade 0: Normal
  Grade 1: Minimal increase but tolerable
  Grade 2: Medium increase but tolerable
  Grade 3: Excessive increase but not tolerable

- Burning Sensation of Hands and Foot

  Grade 0: No burning sensation
  Grade 1: Sometimes noticed
  Grade 2: Intermittently noticed
  Grade 3: Daily noticed
  Grade 4: Continuously noticed

- Excessive Sweating

  Grade 0: Normal sweating after doing normal physical activities
  Grade 1: Medium sweating
  Grade 2: Immoderate sweating
  Grade 3: Extreme sweating just by doing little work

- Generalized Debility

  Grade 0: No Debility
  Grade 1: Sometimes noticed
  Grade 2: Intermittently noticed
  Grade 3: Continuously noticed

2.5 Objective Parameters

Blood sugar FBS, PPBS
Urine sugar

2.6 Trial Drug

The present trial drug has been taken from the reference found in the ancient *Ayurveda* treatise *Charaka Samhita*[10], in the context of the treatment of diabetes (*Prameha Chikitsa Adhaya*). The ingredients which are described are mentioned in Table 1.

Table 1. Ingredients of polyherbal formulation (*Phalatrikadi Vati*)

S. No.	Name Botanical	Proportion
1	*Terminalia chebula*	1 part
2	*Terminalia bellarica*	1 part
3	*Embcica officinalis*	1 part
4	*Berberis aristata*	1 part
5	*Cirullus colocynthis*	1 part
6	*Cyperus rotundus*	1 part
7	*Curcuma longa*	1 part

2.6.1 Procurement and Preparation of the Formulation

All the ingredients are well identified and raw drugs were procured from Kajarekar Ayurveda Pharmacy Belgaum, Karnataka. The raw drugs were authenticated by the Dravyaguna department. Tablets were prepared after fortification with the Polyherbal formulation *kwatha* at Pavaman Pharmacy, Vijayapura.

2.7 Posology of Trial Drug

Internally: 2000 mg, 2tab BD with Water, *Vati* dose is 12gm, as in this *vati* was prepared after fortifying with *Phalatrikadi kwatha*.

Time of medicine consumption: Before food.
The study duration of the Trial drug.
The clinical study was conducted for 30 days.
Follow up – 30 days after completion of study duration.

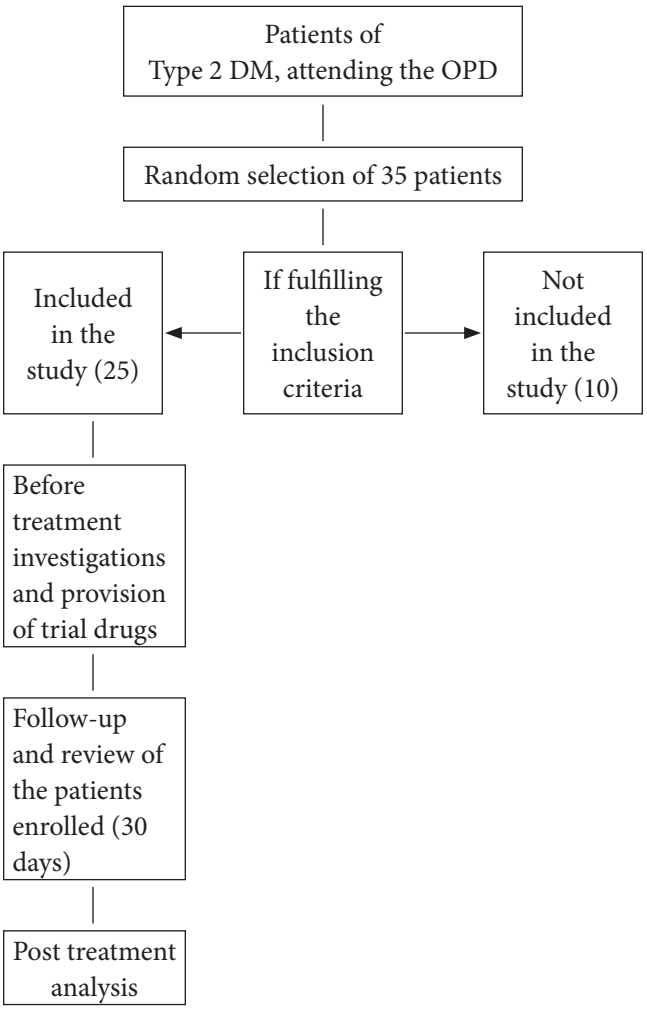

Figure 1. Consort chart of study.

Table 2. Demographic data

Demographic profile (n = 25)	n(%)
Sex	
Male	14 (56)
Female	11 (44)
Age (in years)	
35 years – 45 years	8 (32)
46years – 55years	9 (36)
56years – 65years	8 (32)
Occupation	
Deskwork	12 (48)
Fieldwork	04 (16)
House-wife	09 (36)
Others	-
Economic Status	
Below poverty line	12 (48)
Above poverty line	13(52)
Diet	
Vegetarian	19 (76)
Mixed diet	06 (24)

3. Observations and Results

25 patients were registered for trial and completed the study. The majority numbers of patients i.e. 36% were from the age group of 46-55 and 32% of patients were from the age group of 56-65 years. The study showed that the individual gets affected by Diabetes Millets type 2 after 4 decades. 56% of patients were males and 44% of patients were females. The maximum patient i.e. 96% were Hindus; this is because Hindus dominated the area of the study. Maximum numbers of patients i.e. 76% were vegetarians, whereas 24% of patients had mixed diets which was due to Hindus being the larger part of the study and they were vegetarians. In the present study, 80% of patients had a family history and the maximum number of patients had a sedentary lifestyle i.e. 56%. The etiological factors quoted in the classics were elicited by questioning in the present study. Among them, it was observed that most of the participants were taking rice (less than one-year old) and sweet dishes (prepared by using jaggery, sugar, frequency of taking sweets every month), oily food formed a major portion of food i.e. 100%. About 76% of them were taking curd regularly. In 100% of patients, Metabolism was seen to be impaired as assessed by *Ayurveda* parameters (*Agnibala*).

Among lifestyles, lack of exercise and day sleep was found in 56% of patients. Lack of physical activity was found in 52% of patients. These suggest that data is in correspondence with the causative factors described by classics for the disease Type 2 DM. In prodromal syndrome, weakness was found in 84% of patients and dryness of mouth was found in 32% of patients, urine sugar was found in 100% of patients. Among chief complaints, 100% of patients were having polyuria both in terms of quantity as well as frequency.

To compare the effectiveness of the trial drug before and after the treatment the statistical analysis used was student paired t-test, assuming that the drug is not responsible for changes in the reading before and after the treatment.

Table 3. Statistical analysis of polyherbal formulation on subjective and objective parameters

Parameter	Mean difference	SD	SE	t value	P value	Remark
Avila mootrata	1.24	0.925	0.185	6.698	<0.001	HS
Karapada daha	0.64	0.637	0.127	5.018	<0.001	HS
Kshudhad-hikyata	1.84	0.687	0.137	13,372	<0.001	HS
Pipasa	1.96	0.6110	0.122	16.039	<0.001	HS
Atisweda	1.12	0.7810	0.156	7.170	<0.001	HS
Dourbalya	2.0	0,816	0.163	12.247	<0.001	HS
Prabhoota Mootrata	2.08	0.571	0.114	18.196	<0.001	HS
FBS	31.84	16.754	3.350	9.501	<0.001	HS
PPBS	63.92	39.159	7.831	8.162	<0.001	HS
FUS	0.36	0.3685	0.0737	4.883	<0.001	HS
PPUS	0.54	0.518	0.103	5.204	<0.001	HS

In the present study, 68% relief was observed in polyuria. Urine turbidity was found in 80% of patients for which *Ayurveda* has emphasized that this turbidity of the urine is because of its annexation with the *Dhatu*. *Phalatrikadi Vati* provided 56% relief in urine turbidity. Polyphagia provided 76% relief in polyphagia. Polydipsia showed an 84% reduction in polydipsia. Polyuria causes excessive loss of fluids from the body leading to polydipsia and generalized debility showed a 60% reduction. Satisfying the modern diagnostic criteria i.e. polyuria,

polydipsia, polyphagia, but clinically patients came with only one or no symptoms so only blood sugar criteria are decisive for the diagnosis. FBS before treatment (0^{th} day) mean score was 156.71 and after treatment (on the 30^{th} day) 124.87 (P<0.001) and PPBS before treatment (0^{th} day) mean score was 265.85 and after treatment was (on 30^{th} day) 201.34 (P<0.001) have shown highly significant results. The tablet *Polyherbal* formulation provided a mean difference of 31. 84 mg relief in Fasting Blood Sugar and 63.92 mg mean difference relief in PPBS at statistical level P<0.01 (Table 3).

4. Probable Mode of Action

Clinical and experimental studies depict that *Emblica officinalis*, *Curcuma longa*, the combination of *Terminalia chebula*, *Terminalia bellirica* and *Emblica officinalis* reduces blood glucose significantly. Insulin resistance, hyperglycemia, hyperlipidemia, and islet apoptosis and necrosis properties of curcumin present in *Curcuma longa* help in the treatment and prevention of diabetes mellitus. Curcumin also helps in treating diabetes and diabetic disorders, which include adipocyte dysfunction, neuropathy, nephropathy, vascular diseases, and pancreatic β cell dysfunction[11]. In type 2 diabetes, the consumption of more carbohydrates, there is an increase in postprandial blood glucose level, breakdown of these carbohydrates by the digestive enzymes (*alpha*-amylase and *alpha*-glucosidase), and the reduced ability of cells to take in glucose from the blood result in elevation of blood glucose level. Past studies report that a combination of *Terminalia chebula, Terminalia bellirica* and *Emblica officinalis* inhibit digestive enzymes and can even decrease the absorption of glucose through glycolytic enzymes, thereby reducing blood glucose levels. A study has shown the inhibitory property of a combination of *Terminalia chebula, Terminalia bellirica* and *Emblica officinalis* on pancreatic glycolytic enzymes (*alpha*-amylase and *alpha*-glucosidase) which break down larger polysaccharides into glucose molecules that enter the blood stream[12]. A combination of *Terminalia chebula, Terminalia bellirica* and *Emblica officinalis* inhibits the digestion and absorption of starch, and as a result, it decreases postprandial hyperglycemia. Berberine in *Berberis aristata* helps in lowering blood glucose levels in the blood and improves insulin sensitivity and promotes the uptake of glucose by cells and tissues. A study showed that *B. aristata* extract has a strong potential to regulate glucose homeostasis via decreased blood glucose, and increased glycogen content[13]. This metabolic correction of blood glucose level by the ingredients of the trial drug helped in alleviating the hyperglycemia and thereby reducing the subjective complaints.

5. Conclusion

The selected polyherbal combination of the drug has shown effective treatment in Type 2 DM. It was found that in borderline cases, the sugar levels came to normal, but in cases with levels near the upper limit of the range, they did not return to the normal limits. This may give a hint about a probable requirement for an extension in the duration of treatment. The polyherbal formulation is a safe intervention and can be expected to reduce the symptoms of Type 2 Diabetes Mellitus and blood sugar levels. Future studies with larger sample sizes, longer duration of intervention and follow up needed for more accurate and reliable results.

6. References

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