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Research Article

EFFICACY OF CHANDRAPRABHA VATI WITH GLIMEPIRIDE IN NEWLY DIAGNOSED TYPE 2 DIABETES PATIENTS: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Objectives: The objective of the study was to evaluate the therapeutic potential of Chandraprabha Vati with glimepiride as an add-on therapy in newly diagnosed diabetes mellitus (DM) patients.

Methods: A 6-month, open-label, randomized clinical trial was conducted on 60 newly diagnosed Type 2 DM (T2DM) patients. Participants were divided into two groups: Group 1 received glimepiride 1 mg daily, and Group 2 received glimepiride 1 mg plus chandraprabha vati 250 mg daily. Glycemic parameters (fasting blood sugar [FBS], postprandial blood sugar [PPBS], glycated hemoglobin [HbA1c]) were measured at baseline, 12 weeks, and 24 weeks.

Results: Group 2 showed significant reductions in FBS, PPBS, and HbA1c compared to Group 1 at both 12 and 24 weeks.

Conclusion: In this study, chandraprabha vati as an adjunct to glimepiride significantly improves glycemic control in newly diagnosed T2DM patients. These findings support the integration of Ayurvedic for diabetes management but careful monitoring is required since the plant compounds may cause adverse reactions in some people with less tolerance.

Keywords: Diabetes mellitus, Chandraprabha vati, Ayurvedic formulation, Integrative medicine, Hypoglycemic effect.

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INTRODUCTION

Diabetes mellitus (DM) is a metabolic disorder of long duration, characterized by defects in insulin production, action of insulin, or both leading to an increase in glycemic level. Of the many forms of diabetes, the global cases of Type 2 DM (T2DM) constitute about 90% of all cases [1]. The rising global prevalence of T2DM has been linked to changes in lifestyle, such as less physical activity, poor diet, and genetic susceptibility [2,3]. If not controlled, T2DM can cause serious complications such as nephropathy, retinopathy, neuropathy, and cardiovascular diseases that impose substantial health and economic burdens [4].

The pathophysiology of T2DM is complex and encompasses insulin resistance in peripheral tissues and progressive dysfunction of pancreatic beta-cells. Lifestyle interventions, including dietary and increased physical activity, are the important factor in managing T2DM. Nevertheless, a large majority of patients need pharmacological therapies to attain appropriate glycemic control. Among the pharmacological interventions, sulfonylureas, like glimepiride, have been widely utilized oral hypoglycemic drugs because of their potential to induce insulin secretion from pancreatic beta-cells [5]. Although useful, long-term administration of these agents is usually linked with negative effects such as hypoglycemia, weight gain, and beta-cell fatigue, constraining their long-term use in the control of diabetes [6]. These difficulties make it necessary to investigate complementary and alternative therapeutic interventions that provide enhanced glycemic control with fewer side effects [7].

Over the past few years, there has been increasing interest in combining traditional Ayurvedic medicine with contemporary pharmacotherapy for the treatment of many long-term medical conditions, such as T2DM. Chandraprabha Vati, a polyherbal Ayurvedic formulation, has been used traditionally for centuries in the management of metabolic syndromes, including diabetes. The formulation is a combination of medicinal herbs and minerals that are well-known for their therapeutic effects. Its reported anti-hyperglycemic, anti-inflammatory, and antioxidant activities imply its potential to augment pancreatic beta-cell function, enhance insulin sensitivity, and counteract oxidative stress [8-10]. In addition, research has pointed out the capacity of chandraprabha vati to modulate lipid metabolism and overall metabolic health, rendering it a potential adjunct therapy for T2DM.

The idea of synergistic interactions between herbal preparations and allopathic drugs has been in focus in recent years. These combinations are thought to enhance therapeutic benefits with reduced side effects [11,12]. In the case of T2DM, Ayurvedic preparations such as chandraprabha vati when used in combination with conventional antidiabetic medications like glimepiride can provide a comprehensive strategy for the management of the disease. The advantages could be improved glycemic control, less oxidative stress, and prevention of diabetes complications [13,14].

The current research was conducted to assess the therapeutic efficacy of chandraprabha vati as an add-on treatment with Glimepiride in new-onset T2DM patients. In particular, the research was conducted to compare the effect of glimepiride alone and in combination with chandraprabha vati on primary glycemic markers, such as fasting blood sugar (FBS), postprandial blood sugar (PPBS), and glycated hemoglobin (HbA1c). This study aims to give some insight into the integration of classical Ayurvedic medicine with contemporary pharmacotherapy for efficient diabetes treatment.

METHODS

Aim

The aim of the study was to study the therapeutic potential of glimepiride versus chandraprabha vati as an add-on therapy with glimepiride on glycemic control.

Objective

The objective of the study was to compare the difference between baseline, 3rd month, and 6th month values of FBS, PPBS, and HbA1c.

Inclusion criteria

Patients of either sex in the age group of 18–70 years with newly diagnosed T2DM will be included in the study. Patients having baseline HbA1c >7 will be included in the study. Patients willing to give informed written consent.

Exclusion criteria

Patients diagnosed with Type 1 DM, hepatic or renal impairment, and heart disease. Patients with a history of malignancy. Patients taking any other drugs that can affect Cytochrome P450 metabolism. Patients with psychiatric disorders.

Study design and procedure

This was a 6 months prospective open-label parallel randomized study, with a population of 70 newly diagnosed diabetes male patients from outpatient department of general medicine. Preliminary Test for inclusion was check and selected (Fig. 1). The selected diabetic patients are randomized into two groups, Baseline FBS, PPBS, and HbA1c will be measured. One group is treated with glimepiride 1 mg and other group is treated with chandraprabha vati 250 mg+glimepiride 1 mg for 6 months. Follow-up of the patients to be done ton 3rd and 6th month, FBS, PPBS, and HbA1c should be measured by collecting the samples. Monitoring the incidence of side effects and adverse drug reaction will be done for all the patients.

Statistical analysis

The collected data were analyzed with GraphPad Prism statistics software 23.0 version. Unpaired t-test was used baseline parameters, 2-way analysis of variance (multiple comparison) was used for within the group parameters for both the groups, unpaired t-test was used for comparing parameters in between groups, a probability value of <0.05 is considered significant.

Ethical consideration

The study protocol was submitted to SRM Medical College Hospital and Research Centre and SRM Institute of Science and Technology, Kattankulathur Ethics Committee. The committee approved the protocol after the presentation (approval No. 8745/IEC/2023). The trail is registered in the Clinical Trail Registry of India (Ref.no: CTRI/2024/04/065273).

RESULTS

Baseline characteristics

The baseline characteristics of the study population are shown in Table 1. The Chi-square test showed no significant differences for any parameter between Group A and Group B (p>0.05). This verifies that the groups were well-matched at baseline (Table 1).

Group 1: Estimation of Glucose Parameters

FBS shows a significant reduction at only 24th week. At 24th week, PPBS and HbA1C levels found to be statistically significant when compared with baseline (Table 2).

Group 2: Estimation of glucose parameters

FBS: Marked decrease was seen from the baseline level of 170±3.9 mg/dL to 156.9±9.9 mg/dL at the 12th week (p=0.0413*). FBS was decreased even more by the 24th week to 149±10.1 mg/dL with an extremely significant change (p=0.006**).

Table 1: Baseline characteristic of the study population

Parameters	Group A (n=21)	GroupB (n=23)	p-value
Age (years)	37.9±5.1	37.7±4.8	1.09
Height (cm)	154.6±4.42	155.5±5.1	0.6
Body weight (kg)	76.9±6.3	77.43±7.6	0.8
BMI (kg/m^2)	28.0±2.9	27.6±4.1	1.32
Blood pressure			
Systolic blood pressure (mmHg)	127.3±8.2	126.4±6.5	0.76
Diastolic blood pressure (mmHg)	83.5±4.5	83.2±5.8	2.24
Blood glucose parameters			
FBS (mg/dL)	172.5±5.06	170±3.9	0.388
PBS (mg/dL)	191±4.3	194.3±4.26	0.438
HbA1c (%)	7.54±4.2	7.57±1.9	0.671

#The represented values were expressed in mean±SD. p≤0.05* was considered as statistically significant. BMI: Body mass index, FBS: Fasting blood sugar, PPBS: Postprandial blood sugar, HbA1c: Glycated hemoglobin

Table 2: Comparing 12th and 24th week values of FBS, PPBS and HbA1C (Group 1)

Parameters	Baseline	12th week	p-value	24th week	p-value
FBS (mg/dL)	172.5±5.06	166.1±7.3	1.1038	158.3±9.3	0.0110*
PPBS (mg/dL)	191±4.3	185.8±6.4	0.204	183.5±7.16	0.0473*
HbA1c (%)	7.54±4.2	7.3±1.3	0.710	7.14±0.4	0.044*

#The represented values were expressed in changes in Mean±SD. p≤0.05* was considered as statistically significant, FBS: Fasting blood sugar, PPBS: Postprandial blood sugar, HbA1c: Glycated hemoglobin

PPBS: There was a significant decrease from 194.3±4.26 mg/dL at baseline to 183±9.8 mg/dL at the 12th week (p=0.029*). It continued at the 24th week to 173±13.8 mg/dL (p=0.001**).

HbA1c: While no change occurred in the 12th week (p=0.112), HbA1c values improved by the 24th week significantly, decreasing from 7.57±1.9% to 6.7±4.3% (p=0.002**).

These findings reflect a notable improvement in blood sugar level over time, especially at the 24th week (Table 3).

Group 1 versus Group 2: Comparing glucose parameters

FBS: Group 1 at the 12th week had an FBS average of 166.1±7.3 mg/dL, whereas Group 2 was 156.9±9.9 mg/dL, which was significant (p=0.030*). At the 24th week, FBS decreased further to 158.3±9.3 mg/dL in Group 1 and 149±10.1 mg/dL in Group 2 (p=0.043*).

PPBS: PPBS level had a significant decrease in Group 2 (p=0.048*) at 24th week.

HbA1c: At week 24, HbA1c levels were significantly improved in Group 2 (p=0.016*).

Generally, the results indicate a better control of blood sugar in Group 2 over time (Figs. 2-4).

DISCUSSION

The current study assessed the effect of the intervention on glycemic control by measuring FBS, PPBS, and HbA1c at baseline and 12 and 24 weeks between two groups. The findings imply an improvement in blood glucose control, especially in Group 2, reflecting a greater effect of the intervention among this group.

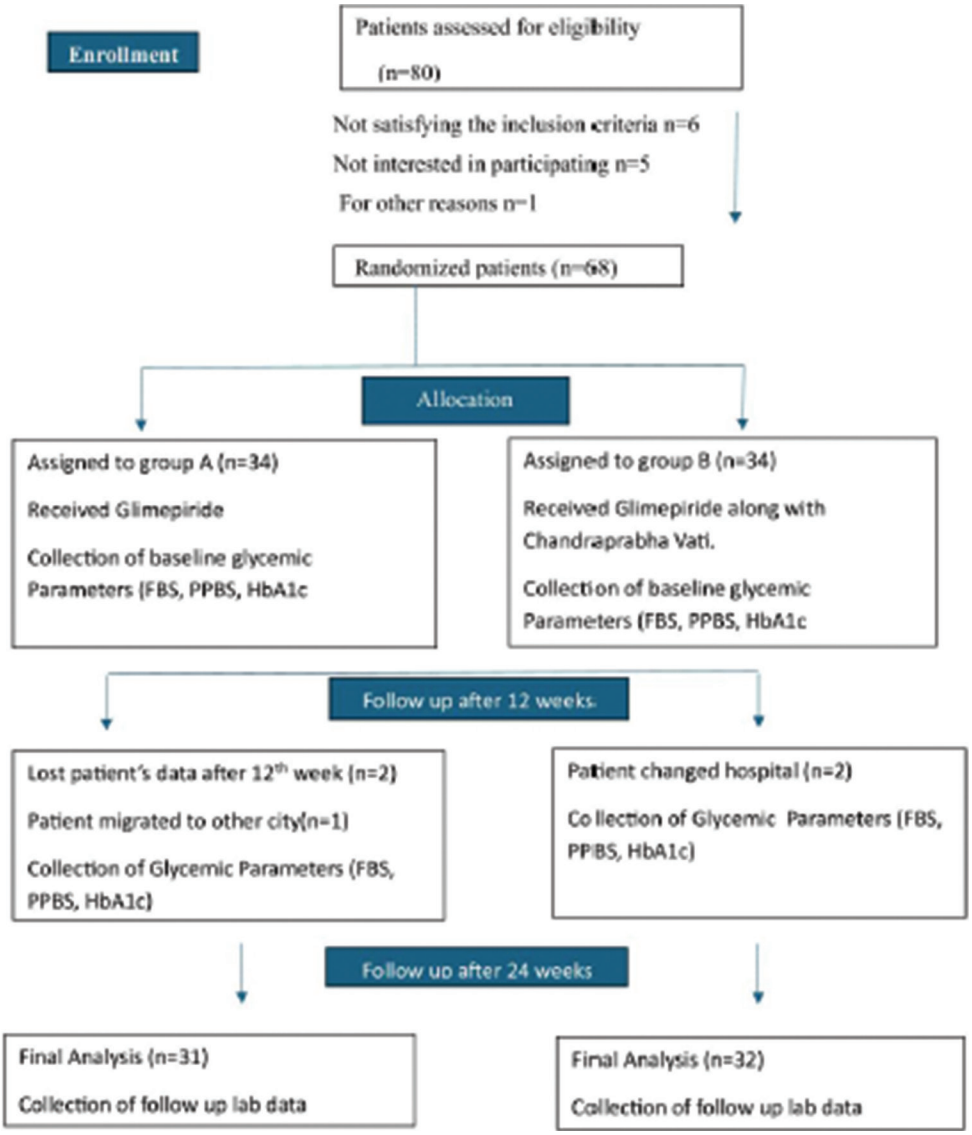

Fig. 1: Consort flow chart of the study

Table 3: Comparing 12th and 24th week values of FBS, PPBS, and HbA1C with baseline (Group 2)

Parameters	Baseline	12th week	p-value	24th week	p-value
FBS (mg/dL)	170±3.9	156.9±9.9	0.0413*	149±10.1	0.006**
PPBS (mg/dL)	194.3±4.26	183±9.8	0.029*	173±13.8	0.001**
HbA1c (%)	7.57±1.9	7.3±6.7	0.112	6.7±4.3	0.002**

#The represented values were expressed in mean±SD. $P \leq 0.05$* was considered as statistically significant, FBS: Fasting blood sugar, PPBS: Postprandial blood sugar, HbA1c: Glycated hemoglobin

Baseline characteristics

The baseline features of the study population showed no significant variation between Group A and Group B, as verified by the Chi-square test (p>0.05). This shows that both groups were well-matched at the beginning of the study, ruling out bias due to demographic and clinical variations. Such matching of baseline features is critical for guaranteeing the validity of interventional studies [15].

Changes in FBS

The FBS values at baseline in Group 1 and Group 2 were similar (p=0.388). Group 2 showed a significant fall in FBS from 170±3.9 mg/dL to 156.9±9.9 mg/dL at the 12th week (p=0.0413), and then further to 149±10.1 mg/dL at the 24th week (p=0.006*). For Group 1, the same trend was evident, but only statistical significance at week 24 (p=0.0110) was recorded.

This trend concurs with evidence from past research assessing the impact of herbal treatment and Ayurvedic compounds on blood glucose. For instance, Chandrasekaran *et al*. illustrated that polyherbal formulations significantly reduced FBS levels with the passage of time [15]. In the same way, a randomized controlled trial by Patel *et al*. indicated that a mixture of natural extracts notably decreased FBS levels at weeks 12 and 24 when compared to the baseline [16].

PPBS trends

PPBS levels also had a similar trend, with a remarkable decrease in Group 2 at the 12th and 24th weeks. Baseline PPBS was 194.3±4.26 mg/dL, which decreased to 183±9.8 mg/dL at the 12th week (p=0.029) and again to 173±13.8 mg/dL at the 24th week (p=0.001**). In Group 1, the reduction in PPBS was not significant at the 12th week (p=0.204) but became significant at the 24th week (p=0.0473*).

This aligns with the results of Balasubramaniam *et al*., who noted a marked decrease in PPBS levels among diabetic patients receiving herbal preparations over a period of 24 weeks [17].

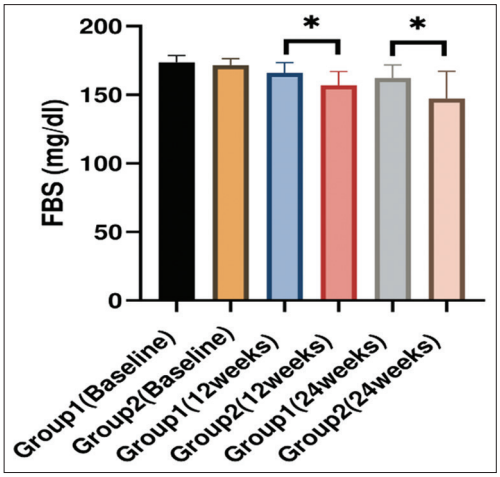

Fig. 2: Comparison of fasting blood sugar values of Group 1 and Group 2

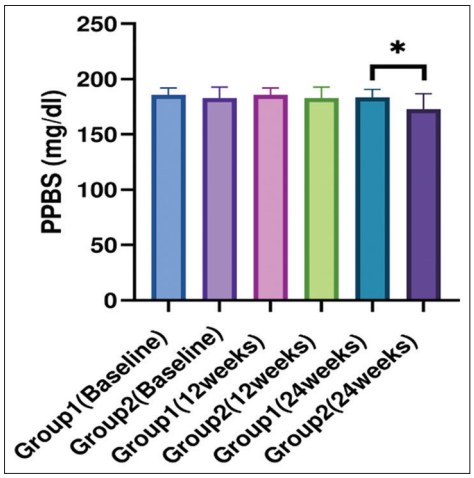

Fig. 3: Comparison of postprandial blood sugar values of Group 1 and Group 2

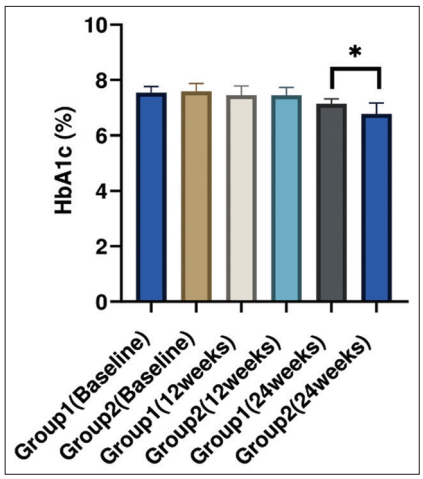

Fig. 4: Comparing glycated hemoglobin values of Group 1 and Group 2. *Represented p≤0.05* considered as statistically significant

HbA1c values, as a marker of long-term glycemic control, showed a significant reduction in Group 2. HbA1c values at baseline were similar in both groups (p=0.671). Group 2 had a non-significant change at the 12th week (p=0.112), but by the 24th week, HbA1c significantly decreased from 7.57±1.9% to 6.7±4.3% (p=0.002**). In Group 1, the statistically significant difference was observed only at the 24th week (p=0.044*).

These results are consistent with the outcomes of earlier clinical trials proving the efficacy of plant or herbal formulations in enhancing long-term glycemic control [18].

Comparison between Group 1 and Group 2

A comparison between the two groups directly revealed that Group 2 had better glycemic control. At the 12th week, Group 2 had lower FBS levels compared to Group 1 (p=0.030), a trend that continued at the 24th week (p=0.043). Although PPBS levels were not significantly different at the 12th week (p=0.438), they declined significantly in Group 2 by the 24th week (p=0.048). HbA1c levels also adhered to this trend, being statistically significantly decreased in Group 2 at the 24th week (p=0.016).

This augmented effect in Group 2 could be due to variations in intervention dosage, compliance, or synergistic interactions with other lifestyle elements. Mishra *et al.* in his study indicated that the addition of certain bioactive compounds to conventional medicine preparations could improve glycemic control, and the results of the current study are in agreement with this [19].

Clinical implications and future directions

The reductions in FBS, PPBS, and HbA1c observed in this study indicate that the intervention implemented in Group 2 may be a good strategy for diabetes management. These findings confirm earlier research that has stressed the utility of herbal and alternative medicine in regulating blood sugar levels. Future studies must include a larger population, a longer duration of follow-up, and more biomarkers to validate these observations.

In addition, investigation into mechanistic pathways for such effects, including insulin sensitivity, β-cell function, and inflammatory markers, would unveil greater insights into the benefits observed. Investigations by Xu *et al.* and Wang *et al.* have highlighted molecular-level studies to determine the exact role of natural formulations in the management of diabetes [20,21].

CONCLUSION

The findings of this study demonstrate that chandraprabha vati, when used as an adjunct to glimepiride, significantly improves glycemic control in newly diagnosed T2DM patients. The combination therapy not only resulted in substantial reductions in FBS, PPBS, and HbA1c but also highlighted the potential of Ayurvedic formulations to complement conventional medicines effectively. The antioxidant, anti-inflammatory, and insulin-sensitizing properties of Chandraprabha Vati likely contributed to these outcomes, emphasizing the value of integrative medicine approaches in diabetes management. These results support further exploration and application of such synergistic therapies to enhance patient outcomes and address the limitations of single-agent treatments in T2DM.

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AUTHOR'S CONTRIBUTIONS

Study Conceptualization, Formal Analysis, and Supervision: Vijayakumar TM. Data curation software handling and analysis were performed by Ahalya SP. The first draft of the manuscript was written by Ahalya SP, Reviewing and editing. Done by Satish Kumar RC. All authors read and approved the final manuscript.

DECLARATION STATEMENT

This manuscript is original, has not been published or submitted elsewhere, and has been approved by all authors and relevant authorities. It will not be published in any other form without the copyright holder's consent.

CONFLICTS OF INTEREST

There are no conflicts of interest.

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