

A Randomized Multicenter Double-blind Placebo-controlled Prospective Study to Evaluate the Efficacy and Safety of Magnesium + Vitamin D Supplement as an Add-on Therapy to Oral Hypoglycemic Agents in Type 2 Diabetic Patients



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ABSTRACT

Background: Diabetes mellitus (DM) is a growing global concern, with India projected to have 124.9 million cases by 2045. Magnesium (Mg) and vitamin D (VitD) deficiencies are linked to poor glycemic control. Both nutrients play essential roles in glucose metabolism and insulin function, but their combined supplementation in diabetes management remains underexplored. This study evaluates the efficacy and safety of Mg + VitD supplementation as an adjunct to oral hypoglycemic agents (OHAs) in patients with type 2 diabetes mellitus (T2DM).

Materials and methods: A randomized, multicenter, double-blind, placebo-controlled trial was conducted for 90 days across two hospitals in India. 100 T2DM patients were randomized (1:1) to receive Mg (250 mg) + VitD (600 IU) supplementation or placebo alongside standard OHA therapy. The primary outcome assessed changes in OHA dosage, fasting blood sugar (FBS), and postprandial blood sugar (PPBS). Secondary outcomes included HbA1c, serum insulin, HOMA-IR, Mg, and VitD levels, diabetes symptoms checklist (DSC) score, and quality of life score (SF-36).

Results: By day 90, the test group showed a significant reduction in FBS ($p = 0.01$) and HbA1c ($p < 0.0001$) compared to placebo. Serum Mg levels increased significantly ($p < 0.0001$), while serum insulin also improved ($p = 0.01$). HOMA-IR changes were not significant. SF-36 scores indicated significant improvements in physical function ($p = 0.049$), emotional well-being, and pain ($p < 0.05$). DSC scores showed symptom relief in hyperglycemia ($p < 0.0001$), cardiovascular symptoms ($p = 0.003$), neuropathy ($p = 0.028$), and ophthalmological symptoms ($p = 0.006$). No adverse effects were reported.

Conclusion: Mg + VitD supplementation as an adjunct to OHA therapy significantly improved glycemic control better than OHA therapy alone, HbA1c levels, insulin sensitivity, and quality of life in T2DM patients. The intervention was well-tolerated and may serve as a valuable addition to diabetes management, improving treatment outcomes significantly.

Trial registration: The current study has been duly registered with the CTRI (CTRI/2023/03/050877) (20/03/2023).

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INTRODUCTION

India, the diabetes capital, is expected to have 124.9 million (10.9%) patients by 2045, according to IDF.¹ Studies link micronutrient deficiencies, such as magnesium (Mg) and vitamin D (VitD), due to diet restrictions and medications, to rising diabetes prevalence and poor control, indicated by higher glycated hemoglobin.² Mg acts as a crucial cofactor supporting key enzymes in glucose transport, oxidation, insulin release, and action, activating ATPase and adenylate cyclase enzymes, in pancreatic islets and other tissues.³

Magnesium and VitD independently regulate pancreatic β -cell function, insulin release and sensitivity, and glucose metabolism and control. Deficiencies in these nutrients may compromise these functions and increase the risk of developing type 2 diabetes mellitus (T2DM), its persistence, and complications.⁴ Research indicates that in T2DM, higher

circulating Mg levels are associated with lower blood glucose, HbA1c, and markers of insulin resistance.⁵

Recent systematic reviews and meta-analyses found that oral VitD supplementation significantly reduced fasting blood glucose, HOMA-IR, HbA1c, and improved serum 25(OH) D levels.⁶ Diabetic individuals showed low serum Mg levels, negatively associated with diabetes duration, poor glycemic control, and complications.⁷ A pooled analysis of 24 RCTs demonstrated that Mg as an adjuvant therapy significantly improved serum Mg, fasting blood glucose, HOMA-IR, and HbA1c in T2DM patients.⁸ Additionally, Mg plays a crucial role in VitD absorption, transportation, conversion, activation, and pharmacological action.⁹ An Indian study found that in new-onset T2DM, VitD deficiency was more prevalent, with about 20% individuals being subclinically Mg deficient, with a strong negative correlation

between these deficiencies and HOMA-IR, HbA1c, and specifically HOMA-B. Although this study did not investigate the effect of combined VitD and Mg on glycemic control parameters, the authors recommended routine estimation of VitD and Mg in all newly diagnosed type 2 diabetic patients.¹⁰ Therefore, this study aims to evaluate the efficacy and safety of Mg + VitD combination as an adjunct to standard oral hypoglycemic therapy in T2DM. This has been suggested by many studies showing that nutraceuticals addressing common nutritional deficiencies in type 2 diabetes mellitus may offer promising adjunctive therapeutic options.

MATERIALS AND METHODS

Trial Design

This was a multicentric, randomized, double-blinded, placebo-controlled trial conducted for 90 days at the outpatient departments of Pranav Diabetes Center, Bengaluru, and Care Multispecialty Hospital, Pune. The study was approved by the Institutional Ethics Committees of both centers. 100 participants were recruited into two parallel groups in a 1:1 randomization allocation.

Study Objective

Primary objective: Mean changes in oral hypoglycemic agents (OHAs) dose, fasting,

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and postprandial plasma glucose from baseline to day 90 between groups.

Secondary objectives included mean changes in HbA1c, serum insulin, HOMA-IR, Mg, and VitD levels; symptom improvement [diabetes symptoms checklist (DSC) score]; quality of life (SF-36 score); and safety and tolerability.

Inclusion and Exclusion Criteria

Adults of either sex aged 18–70 years with BMI 23–40 kg/m², diagnosed with T2DM (HbA1c > 6.5%), and receiving OHAs were eligible. Individuals on insulin therapy, glucose-control supplements, with diabetic complications, major systemic illnesses, pregnancy/lactation, corticosteroid therapy, or recent clinical trial participation were excluded.

Methodology

Adults aged 18–70 years with T2DM on standard therapy were enrolled after informed consent and baseline demographic, clinical, and

laboratory assessments. Participants were randomized to receive Mg + VitD or placebo once daily, along with standardized diet and exercise advice. Follow-ups on days 45 and 90 included assessment of vitals, fasting blood sugar (FBS), and postprandial blood sugar (PPBS), adverse events, supplements, and compliance with interim telephonic assessments. SF-36, DSC scores, and laboratory parameters were evaluated at baseline and day 90. Data were analyzed using SPSS Version 24, with compliance ≥80% considered acceptable (Fig. 1).

RESULTS AND OBSERVATION

Demographic Characteristics

Of 108 subjects screened, 5 experienced screen failures and 3 withdrew consent; 100 subjects were enrolled, and all completed the study. Groups were comparable in age, sex, and waist circumference, but BMI differed significantly (placebo: 27.40 ± 4.80 vs test: 25.41 ± 3.29 kg/m², *p* = 0.015).

Assessment of Oral Hypoglycemic Agents Dose

No reduction in OHA dose was recommended for any participant, as FBS and PPBS levels, while trending downward, remained above normal ranges throughout the study.

Assessment of FBS and PPBS

By day 90, the test group demonstrated a significant between-group reduction in FBS (*p* = 0.01). Within-group analysis confirmed a significant reduction in FBS in the test group over time (*p* = 0.03), indicating the potential efficacy of the Mg + VitD supplement in lowering fasting glucose levels on continued supplementation. While the placebo group showed no significant change (*p* = 0.98). PPBS reductions in the test group showed a trend but did not reach statistical significance (*p* = 0.50) (Tables 1 and 2, and Fig. 2).

Assessment of Serum Biochemical Parameters

HbA1c declined significantly within the test group (*p* < 0.0001), with a significant between-group difference at day 90 (*p* = 0.04). Serum Mg increased significantly within the test group (*p* < 0.0001), and serum insulin also improved (*p* = 0.01). HOMA-IR and VitD 25-OH did not show significant changes in either group (Tables 3 and 4, and Figs 3 and 4). Results suggest that Mg + VitD supplementation as an add-on therapy to OHA may improve certain biochemical markers, particularly HbA1c and serum Mg, in type 2 diabetic patients.

Evaluation of the SF-36 Score

By day 90, the test group showed significant improvements across multiple SF-36 domains versus placebo: physical functioning (*p* = 0.049), role limitations due to physical health (*p* = 0.0001), role limitations due to emotional problems (*p* = 0.0008), vitality (*p* < 0.0001), pain (*p* = 0.05), and general health (*p* < 0.0001). Emotional well-being and social functioning did not differ significantly between groups. Overall, Mg + VitD supplementation significantly improved the quality of life in patients with type 2 diabetes.

Diabetes Symptoms Checklist Score

Diabetes symptoms checklist scores demonstrated significant improvements in the test group vs placebo for hyperglycemic symptoms (*p* < 0.0001), cardiovascular symptoms (*p* = 0.003), neuropathy symptoms (*p* = 0.028), and ophthalmological symptoms (*p* = 0.006). Improvements in hypoglycemic and psychological symptoms were noted but did not reach statistical significance. Overall, Mg + VitD supplementation as an add-on to OHA may help improve multiple diabetes-related symptoms.

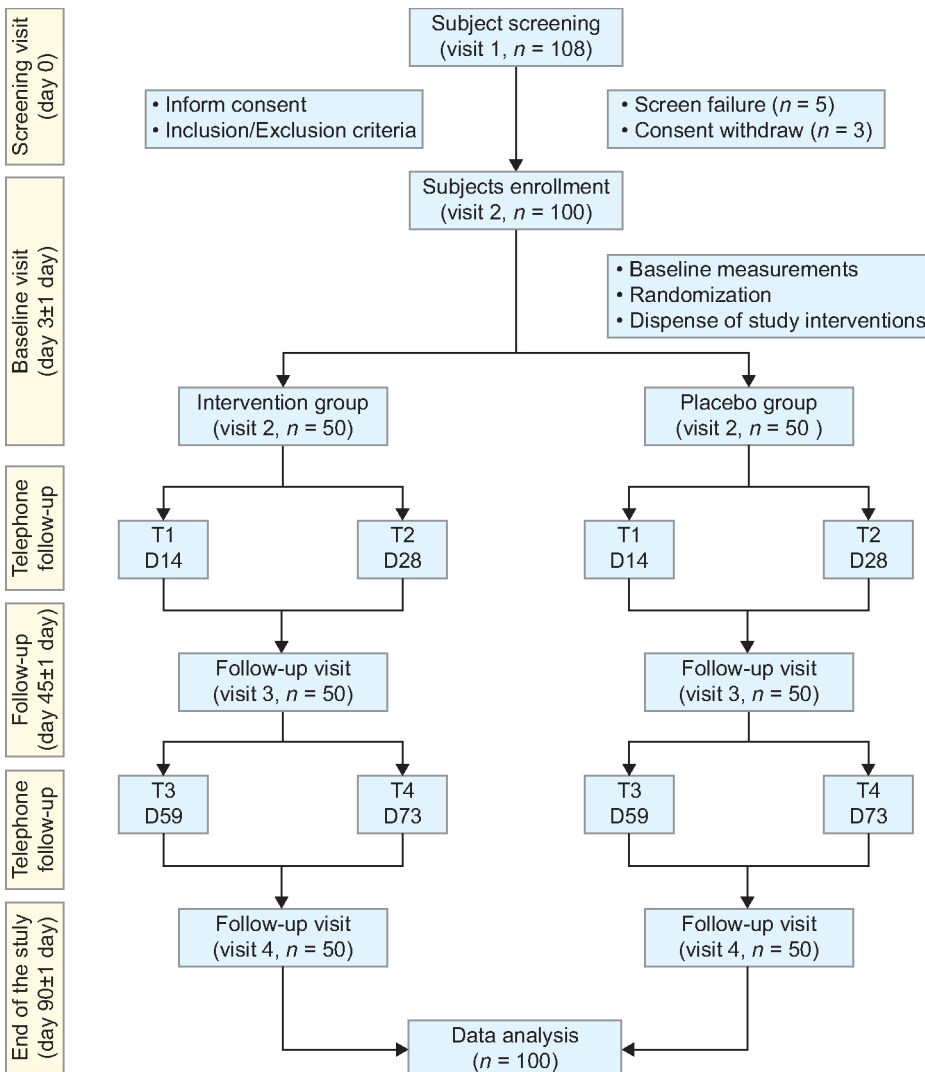
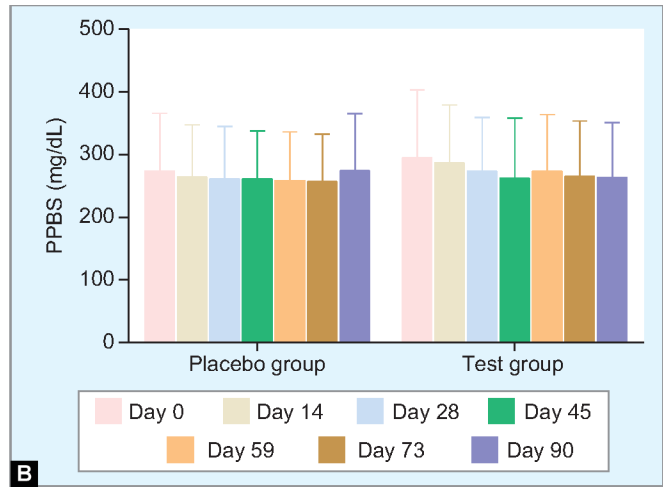
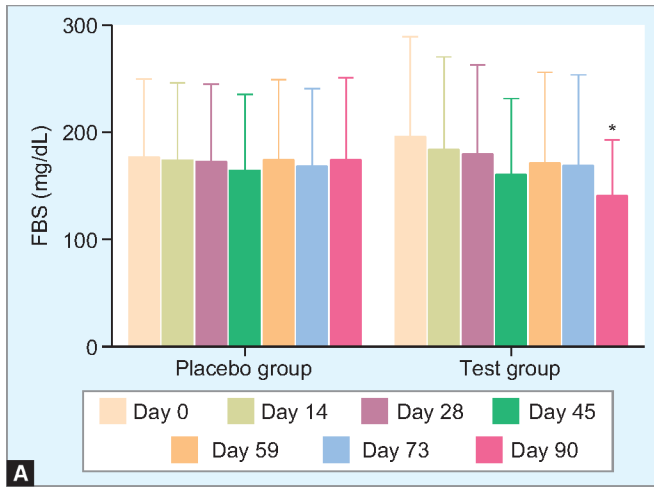
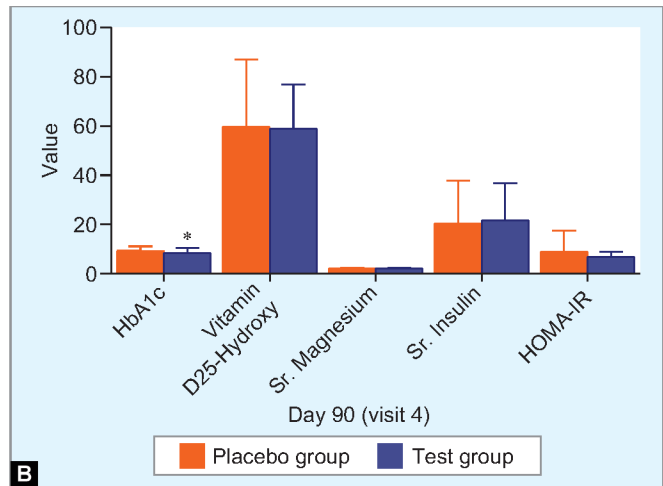
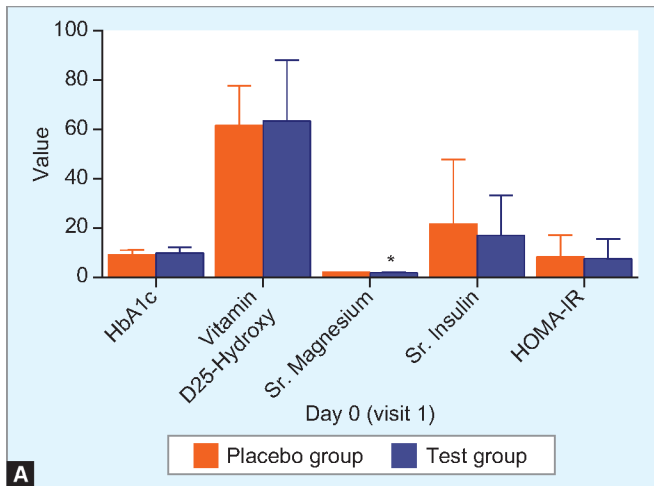


Fig. 1: CONSORT flow diagram



Figs 2A and B: Within-group comparison of mean changes in (A) FBS and (B) PPBS at different assessment points. Statistical analysis was performed using an unpaired *t*-test. Day 0 vs days 14, 28, 45, 59, 73, and 90 (**p* < 0.05)



Figs 3A and B: Between-group comparison of mean changes in different serum biochemical parameters at (A) day 0 (visit 1) and (B) day 90 (visit 4). Statistical analysis was performed using an unpaired *t*-test (Placebo group vs test group; **p* < 0.05)

Table 1: Between-group comparison of mean change in FBS and PPBS at different assessment points

Visits	Placebo group (mean ± SD)	Test group (mean ± SD)	Mean difference	95% CI	<i>p</i> -value
FBS (mg/dL)					
Day 0	176.80 ± 72.7	195.80 ± 93.2	18.96 ± 16.73	-52.20 to 14.28	0.26
Day 45	164.40 ± 70.70	160.40 ± 70.85	4.02 ± 14.16	-24.11 to 32.15	0.78
Day 90	174.30 ± 76.31	140.70 ± 52.20	33.62 ± 13.08	7.634 to 59.61	0.01*
PPBS (mg/dL)					
Day 0	273.8 ± 91.75	294.90 ± 108.0	21.06 ± 20.04	-60.89 to 18.77	0.30
Day 45	261.20 ± 76.33	262.0 ± 96.0	0.84 ± 17.35	-35.31 to 33.63	0.96
Day 90	274.30 ± 90.89	263.50 ± 87.52	10.84 ± 17.84	-24.62 to 46.30	0.54

Statistical analysis was performed by an unpaired *t*-test. Placebo group vs test group; **p* < 0.05

Table 2: Within-group comparison of mean changes in FBS and PPBS from screening to different assessment points

FBS (mg/dL)	Day 0	Day 45	Day 90	<i>p</i> -value
Placebo group (mean ± SD)	176.80 ± 72.72	164.40 ± 70.70	174.30 ± 76.31	0.98
Test group (mean ± SD)	195.80 ± 93.27	160.40 ± 70.85	140.70 ± 52.20	0.03*
PPBS (mg/dL)				
Placebo group (mean ± SD)	273.8 ± 91.75	261.20 ± 76.33	274.30 ± 90.89	0.90
Test group (mean ± SD)	294.90 ± 108.0	262.0 ± 96.0	263.50 ± 87.52	0.50

Statistical analysis was performed using ANOVA; **p* < 0.05

Table 3: Between-group comparison of mean change in different serum biochemical parameters at different assessment points

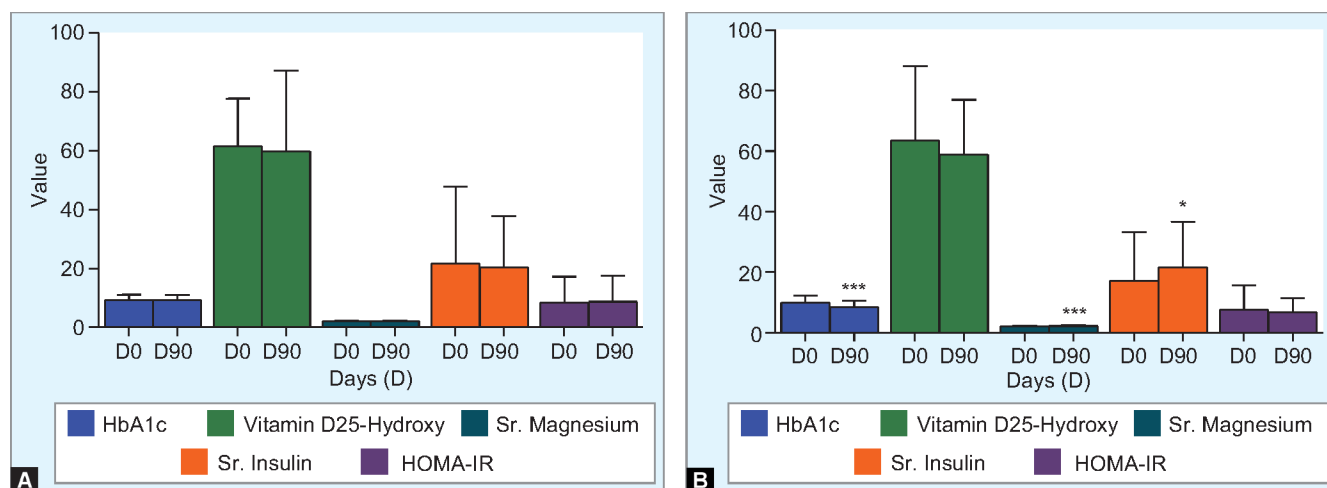
Visits	Placebo group (mean ± SD)	Test group (mean ± SD)	Mean difference	95% CI	p-value
HbA1c					
Day 0	9.24 ± 1.88	9.88 ± 2.37	0.648 ± 0.43	-1.496 to 0.201	0.13
Day 90	9.19 ± 1.87	8.36 ± 2.14	0.830 ± 0.40	0.034 to 1.630	0.04*
Vitamin D25-hydroxy (nmol/L)					
Day 0	61.55 ± 16.11	63.41 ± 24.59	-1.856 ± 4.16	-10.12 to 6.407	0.50
Day 90	59.69 ± 27.41	58.85 ± 18.12	0.84 ± 4.65	-8.392 to 10.07	0.86
Serum magnesium (mg/dL)					
Day 0	2.07 ± 0.22	1.98 ± 0.21	0.09 ± 0.04	0.005 to 0.176	0.04*
Day 90	2.07 ± 0.21	2.14 ± 0.25	0.07 ± 0.05	-0.168 to 0.017	0.14
Serum insulin (µU/mL)					
Day 0	21.78 ± 25.98	17.06 ± 16.17	4.72 ± 4.33	-3.878 to 13.32	0.28
Day 90	20.35 ± 17.45	21.51 ± 15.11	1.16 ± 3.26	-7.650 to 5.325	0.72
HOMA-IR					
Day 0	8.41 ± 8.79	7.60 ± 7.94	0.81 ± 1.68	-2.518 to 4.139	0.63
Day 90	8.75 ± 8.72	6.76 ± 4.51	1.99 ± 1.39	-0.7661 to 4.753	0.15

Statistical analysis was performed by an unpaired t-test. Placebo group vs test group; * $p < 0.05$

Table 4: Within-group comparison of mean changes in different serum biochemical parameters from screening to different assessment points

Group	Day 0	Day 90	Mean difference	95% CI	p-value
HbA1c					
Placebo group (mean ± SD)	9.24 ± 1.88	9.19 ± 1.87	0.042	-0.455 to 0.539	0.87
Test group (mean ± SD)	9.88 ± 2.37	8.36 ± 2.14	1.522	0.937 to 2.107	<0.0001***
Vitamin D25-hydroxy (nmol/L)					
Placebo group (mean ± SD)	61.55 ± 16.11	59.69 ± 27.41	1.86	-5.622 to 9.341	0.62
Test group (mean ± SD)	63.41 ± 24.59	58.85 ± 18.12	4.57	-2.424 to 11.54	0.20
Serum magnesium (mg/dL)					
Placebo group (mean ± SD)	2.07 ± 0.22	2.07 ± 0.21	0.007	-0.092 to 0.078	0.87
Test group (mean ± SD)	1.98 ± 0.21	2.14 ± 0.25	0.165	-0.237 to -0.093	<0.0001***
Serum insulin (µU/mL)					
Placebo group (mean ± SD)	21.78 ± 25.98	20.35 ± 17.45	1.44	-6.013 to 8.890	0.70
Test group (mean ± SD)	17.06 ± 16.17	21.51 ± 15.11	4.45	-7.948 to -0.946	0.01*
HOMA-IR					
Placebo group (mean ± SD)	8.41 ± 8.79	8.75 ± 8.72	0.336	-3.394 to 2.722	0.83
Test group (mean ± SD)	7.60 ± 7.94	6.76 ± 4.51	0.847	-1.038 to 2.733	0.37

Statistical analysis was performed by a paired t-test. Day 0 vs day 90; * $p < 0.05$; *** $p < 0.001$



Figs 4A and B: Within-group comparison of mean changes in different serum biochemical parameters in (A) the placebo group and (B) the test group from screening to the end of the study. Statistical analysis was performed using a paired t-test (day 0 vs day 90; *** $p < 0.001$ and * $p < 0.05$)

Assessment of Body Weight, BMI, and Waist Circumference

The assessment of body weight, BMI, and waist circumference in the study revealed no significant changes between or within groups over the study period.

Safety Analysis

The safety analysis, including physical examinations, vital signs, hematological parameters, serum biochemical parameters, and urinalysis parameters, revealed no significant adverse effects attributable to the intervention.

DISCUSSION

This study demonstrated that Mg + VitD co-supplementation as an adjunct to standard OHA therapy significantly improved glycemic control in T2DM patients. Despite established recommended dietary allowances (370 mg/day in Indian females, 440 mg/day in males), Mg intake is often insufficient, resulting in intracellular Mg deficiency,^{11,12} which can also be a significant contributor to insulin resistance. Low Mg status plays a key role in the pathogenesis of diabetes: there is a graded inverse link between serum Mg and T2DM risk.¹³ However, Mg status does not always correlate with serum Mg because patients with normal Mg levels may even have subclinical intracellular Mg deficiency, because intracellular Mg levels are more representative end points of total body Mg.¹⁴

Diabetes itself induces low Mg status in 10–62.7% of diabetic patients, significantly higher than the 6–17.4% seen in healthy individuals.¹⁵ Contributing factors include enhanced renal Mg loss, glycosuria-induced osmotic diuresis, and metformin, which downregulates the gene expression of Mg transporter TRPM-6, reducing absorption and reabsorption.¹⁶ Inadequate VitD further impairs insulin secretion and increases insulin resistance. Since Mg is a vital cofactor for VitD metabolism, coexisting deficiencies of Mg and VitD worsen glycemic control and reduce OHA efficacy.¹⁷ Thus, to achieve the desired glycemic control, cellular Mg status and VitD deficiency need to be corrected, and they may be supplemented in such patients as an adjunct to the standard therapeutic regimen.

Long-term metformin therapy may downregulate the Mg transporter TRPM6, thereby reducing intestinal and renal Mg absorption. This can lead to subclinical Mg deficiency, may impair VitD action, worsen insulin resistance, and reduce the efficacy of OHA.¹⁸ Therefore, Mg and VitD supplementation may help improve outcomes

in patients with uncontrolled diabetes on metformin-based therapy.

The efficacy analysis demonstrated significant improvement in glycemic control (FBS) in the test group compared to the placebo group. These findings may be attributed to the complementary roles of Mg and VitD in glucose metabolism, insulin secretion, and insulin sensitivity.¹⁹ Mg acts as a cofactor in carbohydrate metabolism, while VitD influences insulin action; deficiencies in either nutrient impair insulin secretion due to impairment of Na⁺-K⁺-ATPase channels, whereby the pancreatic beta-cell functions are compromised.^{20,21}

Postprandial blood sugar levels showed a nonstatistically significant decreasing trend in the test group. The finding differs from some earlier studies reporting significant PPBS improvement with Mg and VitD supplementation,^{22,23} which may be due to variations in baseline VitD status or dietary intake among participants.

Serum biochemical analysis showed a significant reduction in HbA1c by day 90 in the test group, while the placebo group showed no significant change. Similar findings have been reported in earlier studies demonstrating that Mg and VitD supplementation can significantly reduce HbA1c,^{24,25} supporting improved long-term glycemic control despite nonsignificant changes in PPBS. Additionally, serum Mg ($p < 0.0001$) and insulin levels ($p = 0.01$) increased significantly in the test group, whereas no such changes were observed in the placebo group.

Quality-of-life assessment using the SF-36 questionnaire showed significant improvements in the test group compared with placebo across multiple domains. These findings indicate that supplementation significantly improved overall health-related quality of life.

Evaluation using the DSC showed significant improvements in the test group compared to the placebo by day 90. These findings suggest that Mg + VitD supplementation provides comprehensive relief from diabetes-related symptoms.^{26,27} Consistent with earlier reports, our study also demonstrated that supplementation restored serum Mg and improved insulin sensitivity and metabolic control in type 2 diabetes.^{28,29}

Safety analysis, including physical examination, vital signs, hematological/biochemical parameters, and urinalysis, showed no significant adverse effects, indicating good tolerability of the supplementation. Treatment compliance was high (>97%), supporting regimen feasibility. However, the study was limited by a small sample size and short duration (90 days).

CONCLUSION

Mg + VitD supplementation as an adjunct to OHA therapy significantly improved FBS, HbA1c, serum Mg and insulin levels, and overall quality of life in T2DM patients over 90 days, with excellent tolerability and high compliance. These findings support the potential of Mg + VitD as a valuable, safe addition to standard diabetes management. Larger, longer-term trials are needed to validate these preliminary results and to explore dose reduction in OHAs.

DECLARATIONS

Ethics Approval and Consent to Participate

The study protocol complied with the Declaration of Helsinki and other relevant ethical guidelines. Ethical approval was obtained from the Institutional Ethics Committees of Pranav Diabetes Center, Bengaluru, and Care Multispecialty Hospital, Pune, and written informed consent was obtained from all participants.

DATA AVAILABILITY

The data supporting the findings of this study are available from the first author, Dr Sanjay Tandon, upon reasonable request.

SOURCE OF SUPPORT

This research was funded by Pharmed Limited, Bengaluru, Karnataka, India.

CONFLICT OF INTEREST

None.

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AUTHOR'S CONTRIBUTIONS

All authors contributed to the study conception, design, execution, data acquisition, analysis, and interpretation. They also drafted or critically revised the manuscript, approved the final version for publication, and took responsibility for the work.

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