

A comparative evaluation of Imeglimin and Metformin monotherapy in newly diagnosed type 2 diabetes patients

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Abstract

Background: Type 2 Diabetes Mellitus (T2DM) is a chronic metabolic disorder caused by insulin resistance and impaired secretion, affecting millions globally. In India, the prevalence of diabetes is 11.4%. Management includes lifestyle changes and medications like Metformin, which is the first-line treatment. Despite available therapies, glycaemic control remains suboptimal in many patients, leading to the need for combination treatments. Imeglimin is a novel anti-hyperglycaemic agent approved in Japan (2021) and India (2022). It offers a unique mechanism of action by enhancing insulin secretion and decreasing insulin resistance. This study compares the efficacy and safety of Imeglimin versus Metformin in newly diagnosed T2DM patients.

Methods: This was an observational, analytical, open-label, cohort study. A total of 180 newly diagnosed T2DM patients were enrolled, who were not on any medications. Patients were enrolled into two groups of 90 each, depending on the treatment given by the clinician: one group received Imeglimin 500mg/1gm BD, while the other received Metformin 500mg/1gm BD for 6 months. Follow-ups were done at 1,3, and 6 months. The primary outcome was the change in FBS, PPBS, and HbA1c from baseline to 6 months (week 24).

Results: Both groups showed a clinically significant reduction in FBS, PPBS, and HbA1c levels; however, the difference between the two groups was not clinically significant. Both groups experienced a reduction in TC, TG, and LDL with no statistically significant differences between the groups. However, the Metformin group showed a significantly higher increase in HDL compared to the Imeglimin group. Abdominal fullness and constipation were the most common side effects seen in patients in the metformin group. Hypoglycemia was not observed with either Imeglimin or Metformin during the study.

Conclusion: This study suggests that Imeglimin provides glycemic control comparable to Metformin, making it a hopeful alternative for diabetes management.

Keywords: Type 2 diabetes mellitus; Imeglimin; Metformin; HbA1c; efficacy; safety.

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Introduction

Type 2 Diabetes Mellitus (T2DM) is a chronic metabolic disorder characterized by elevated blood glucose levels due to impaired insulin secretion and increased insulin resistance. Millions of people worldwide are impacted by this expanding global health issue.¹ According to the International Diabetes Federation (2025), the number of people with diabetes is predicted to rise from 589 million to 852.5 million by 2050. In India, the prevalence of diabetes is 11.4%.² The prevalence is lowest among adults aged 20 to 24, it is 1.9% reported in 2024 and is expected to accelerate to 2.2% by 2050. Adults aged 75

to 79, on the other hand, had the highest prevalence, estimated at 24.8% in 2024 and expected to rise marginally to 25.4% by 2050.²

T2DM is affected by factors such as obesity, sedentary lifestyles, hypertension, and dyslipidemia. Pathophysiological mechanisms include beta-cell dysfunction, increased insulin resistance, altered adipokine levels, and gut microbiota changes. Effective management demands a combination of lifestyle modifications and pharmacological interventions. Metformin is the first-line treatment, improving insulin sensitivity and reducing glucose production. Additional

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therapies include sulfonylureas, DPP-4 inhibitors, GLP-1 receptor agonists, and SGLT2 inhibitors, with some offering cardiovascular benefits.¹ Despite available treatments, glycemic control remains suboptimal in many patients, necessitating combination therapies. Recent research has introduced Imeglimin, a novel anti-hyperglycemic agent that enhances both insulin secretion and decreases insulin resistance. It is approved to be used in type 2 diabetic patients in Japan (2021) and India (2022)^{3,4}, Imeglimin (IMEG) is the first oral agent from the Glimin class, a group of Tetrahydrotriazine compounds with demonstrated Hypoglycaemic effects. Its chemical name is (6R)-(+)-4-dimethylamino-2-imino-6-methyl-1,2,5,6-tetrahydro-1,3,5-triazine hydrochloride.¹⁴ IMEG acts by inhibiting mitochondrial oxidative phosphorylation, thereby exerting significant metabolic effects.¹⁴ It has a half-life of 10–20 hours in healthy individuals. Absorption involves both passive and active transport and can last up to 6 hours.¹³ Oral bioavailability ranges from 20% to 50%, decreasing with higher doses (100–6000 mg). The drug exhibits biphasic elimination: an initial rapid phase followed by slower clearance. The hepatic metabolism of IMEG is very low, so it is excreted almost completely unchanged in urine.¹² Imeglimin has shown efficacy in phase III trials as monotherapy and combination therapy. However, its real-world effectiveness and safety compared to metformin remain under investigation. Therefore, this study aimed to evaluate the efficacy and safety of Imeglimin versus metformin in newly diagnosed T2DM patients, to determine an alternative treatment option.

Materials and methods

This observational, analytical, cohort, open-label study analyzed the effects of Imeglimin and Metformin as monotherapy in newly diagnosed Type 2 Diabetes Mellitus (T2DM) patients. The study was conducted in the medicine outpatient department of a tertiary care hospital in northern India. After receiving the institutional ethical committee clearance (SNMC/IEC/2024/232), patient enrollment was initiated. Newly diagnosed diabetic patients were enrolled based on inclusion and exclusion criteria. Patients were informed about the study through a patient information sheet, and then written consent was obtained from them. Patients were enrolled into two groups of 90 each, depending on the treatment given by the clinician: one group received Imeglimin 500mg/1gm BD, while the other received Metformin 500mg/1gm BD for 6 months. Study variable data were collected from patient records, and adverse drug reactions were gathered by personal interview during follow-up visits. Patients were followed up at 4 weeks, 12 weeks, and 24 weeks. Those showing improvement continued for 6 months, while non-responders were prescribed dual-drug therapy and excluded. A total of 190 patients (95 per group) were enrolled based on a prevalence-based calculation formula with a 90% confidence level ($z=1.64$) and 5% precision. Patient who met the Inclusion criteria such as all recently diagnosed/ Drug naïve T2DM, fasting blood glucose level: 125mg/dl - 180mg/dl, post prandial level: 200mg/dl - 280mg/dl, HbA1c >6.5% to <9.0%, Age >25

years attending the medicine OPD, patient who are willing to participate voluntarily by signing informed consent were enrolled.

Patient who did not meet the inclusion criteria were excluded, like Patients who were on insulin therapy or type-I diabetes mellitus, Pregnant and lactating women, Patients who have history of Diabetic Ketoacidosis (DKA) /Hyperosmolar Hyperglycemic Non-Ketotic Syndrome (HHNS) in last 6months, Patients suffering from renal or liver disease, Patients with any history of retinopathy, peripheral vascular disease/Gangrene, recent cardiovascular events (<1 year), stroke or has undergone surgery, and suffering with any other comorbid disease.

The patients were advised to follow a low-carbohydrate, high-fiber diet, as it is known to benefit individuals with diabetes mellitus by improving glycemic control and reducing postprandial glucose spikes. It is important for patients to avoid saturated and trans fats, as they can contribute to insulin resistance and increase the risk of cardiovascular complications. They were also advised physical activity such as low-intensity exercise as it is generally safe and effective for those with diabetes, especially if they have comorbid conditions or limited exercise tolerance. Regular activity enhances insulin sensitivity, aids in weight management, and improves overall metabolic health. Individuals with diabetes should aim for at least 30 minutes of physical activity daily, with walking being a recommended option.

Efficacy was determined by the reduction in Fasting Blood Sugar, Post Prandial Blood Sugar and HbA1c. Changes in BMI and lipid profile values were also recorded during the study. Hemoglobin A1c of all the patients was measured using the Beckman Coulter (DxC 700 AU) chemistry analyzer with the ion exchange HPLC, which is approved by the NGSP (National Glycohemoglobin Standardization Program). An electrocardiogram was performed at baseline and the end of the study for all the participants.

Safety was determined by any symptomatic/asymptomatic Hypoglycemic events and adverse events, such as gastrointestinal and any other adverse events.

Statistical analysis

Data analysis was performed using Microsoft Excel and Jamovi (version 2.5) software. T-tests were used to assess differences between groups. Unpaired t-tests with unequal variance determined statistical significance ($p < 0.05$).

Unpaired t-tests were used to analyse the data rather than ANOVA as we were comparing two independent groups and focusing on specific outcome measures at a single final point in time, rather than analyzing multiple time points or multiple groups simultaneously.

Although data was collected at different times during follow-up, the comparisons at each stage involved different variables and were not analyzed longitudinally. At the final stage, we conducted a one-time comparison between the two groups, without accounting for repeated measures across time. Since there were only two groups

and one main comparison point, the unpaired t-test was appropriate.

In contrast, ANOVA (Analysis of Variance) is more suitable when comparing more than two groups, or multiple time points or conditions within the same group (e.g., repeated measures), neither of which applied in our final analysis.

Result:Total number of the 190 enrolled patients, 180 completed the study (90 in the Imeglimin group, 90 in the Metformin group), Five participants dropped out in each group resulting in a dropout rate of 11.11%. Baseline characteristics were comparable in both groups (Table 1).

Table 1: Distribution of sociodemographic profile and gender distribution, glycemc parameters, lipid profile among study participants (N=180)

	Imeglimin Group (n=90)	Metformin Group (n=90)	p = Value
Age	53.6 ± 12.5	52.4 ± 12.5	0.520
BMI	24.3 ± 1.57	24.6 ± 3.78	0.488
Male	50	47	-
Female	40	43	-
Fasting Blood Sugar (mg/dL)	154.1 ± 15.68	153.41 ± 15.759	0.769
Postprandial Blood Sugar (mg/dL)	233.2 ± 23.262	238.18 ± 23.337	0.153
HbA1c (%)	8.32 ± 0.573	8.28 ± 0.578	0.642
TC	193.1 ± 19.63	191.3 ± 19.56	0.539
TG	212.5 ± 26.42	209.4 ± 26.6	0.434
LDL	108.0 ± 14.84	110.1 ± 13.49	0.322
HDL	31.0 ± 30.5	30.9 ± 3.79	0.975

The above table illustrates that out of the total study participants (N=180), the mean age in the Imeglimin group (n=90) was 53.6 ± 12.5 years, while in the Metformin group (n=90), it was 52.4 ± 12.5 years, with a p-value of 0.520. The mean BMI in the Imeglimin group was 24.3 ± 1.57, whereas in the Metformin group, it was 24.6 ± 3.78, with a p-value of 0.488.

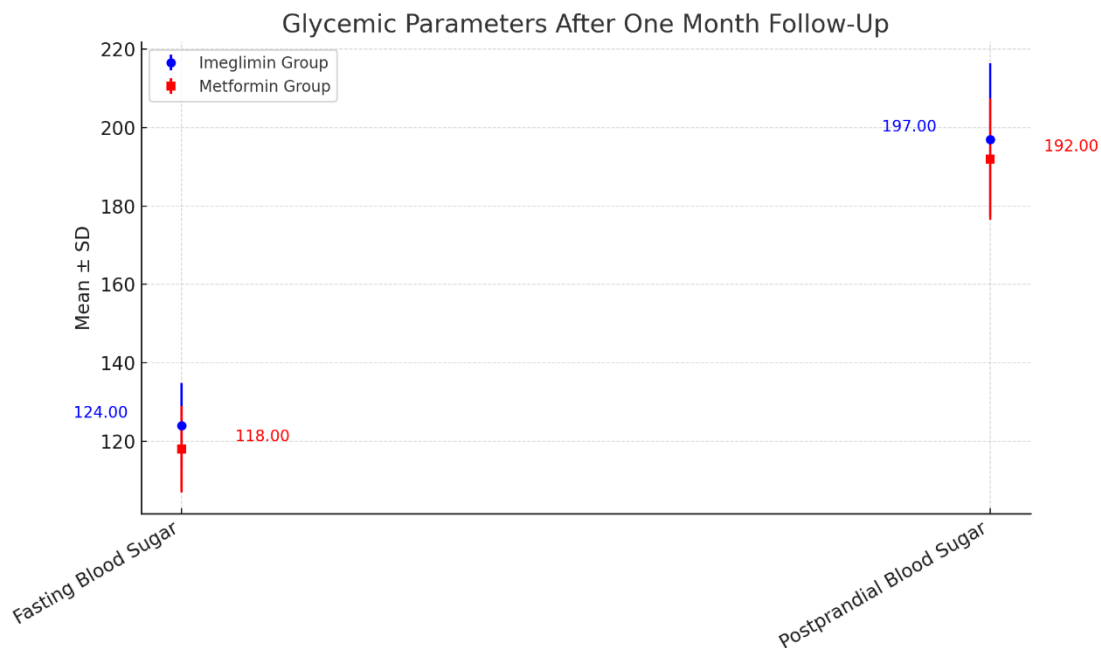
The above table illustrates that out of the total study participants (N=180), in the Imeglimin group, 50 were male and 40 were female, while in the Metformin group, 47 were male and 43 were female. The p-value for gender distribution between the two groups is 0.765.

The baseline fasting blood sugar in the Imeglimin group was 154.1 ± 15.68 mg/dL, while in the Metformin group,

it was 153.41 ± 15.759 mg/dL, with a P value of 0.769. The baseline postprandial blood sugar in the Imeglimin group was 233.2 ± 23.262 mg/dL, while in the Metformin group, it was 238.18 ± 23.337 mg/dL, with a P value of 0.153. The HbA1c in the Imeglimin group was 8.32 ± 0.573% and%, while in the Metformin group, it was 8.28 ± 0.578%, respectively, % with a p-value of 0.642, both were comparable.

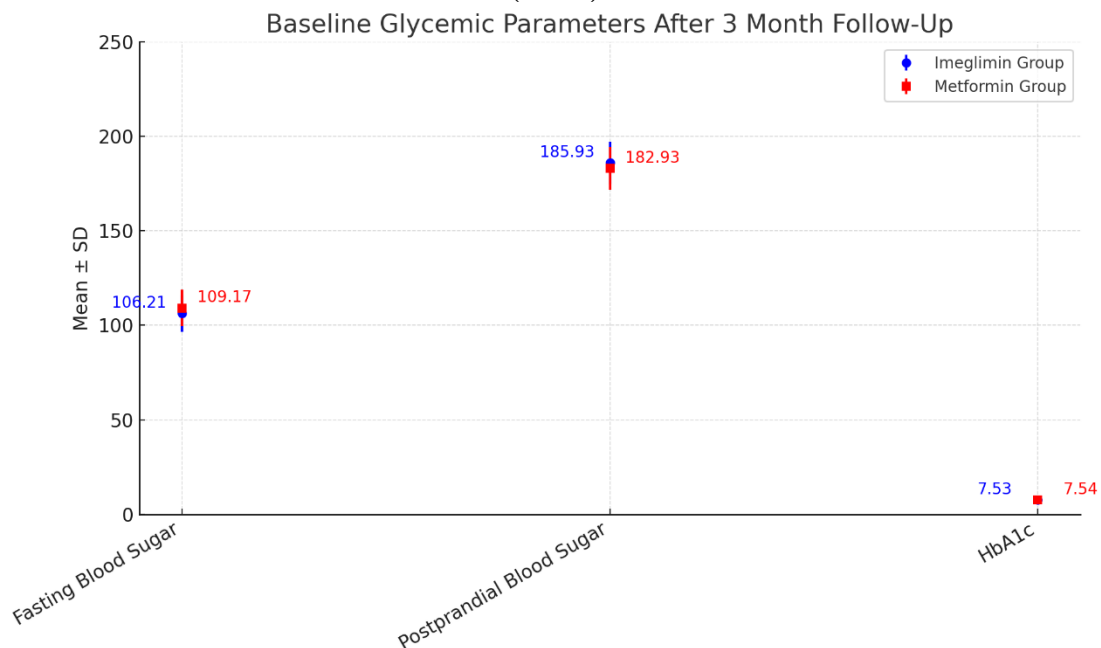
Lipid profile parameters at baseline were also similar between the two groups, with total cholesterol (TC), triglycerides (TG), low-density lipoprotein (LDL), and high-density lipoprotein (HDL) all showing no statistically significant differences (P = 0.539, 0.434, 0.322, and 0.975, respectively)

Figure 1: Distribution of Baseline Glycemc Parameters after 4 weeks of follow-up among study participants (n=180)



At the 4th week follow-up visit, fasting blood sugar was significantly lower in the Metformin group (118.0 ± 11.0 mg/dL) compared to the Imeglimin group (124.0 ± 10.9 mg/dL) ($P = 0.000$). However, postprandial blood sugar was similar between the groups, with no significant difference ($P = 0.058$).

Figure 2: Distribution of Baseline Glycemic Parameters after 12 weeks of Follow-Up among study participants (n=180)



At 12 weeks of week follow-up, the trend reversed slightly, with fasting blood sugar being lower in the Imeglimin group (106.21 ± 9.53 mg/dL) compared to the Metformin group (109.17 ± 9.543 mg/dL), reaching statistical significance ($P = 0.039$). However,

postprandial blood sugar remained comparable ($P = 0.075$) and HbA1c levels were almost identical in both groups ($P = 0.917$), suggesting similar glycemic control at this point

Figure 3: Distribution of Baseline Glycemic Parameter after 24 weeks Follow-Up among study participants (n=180)

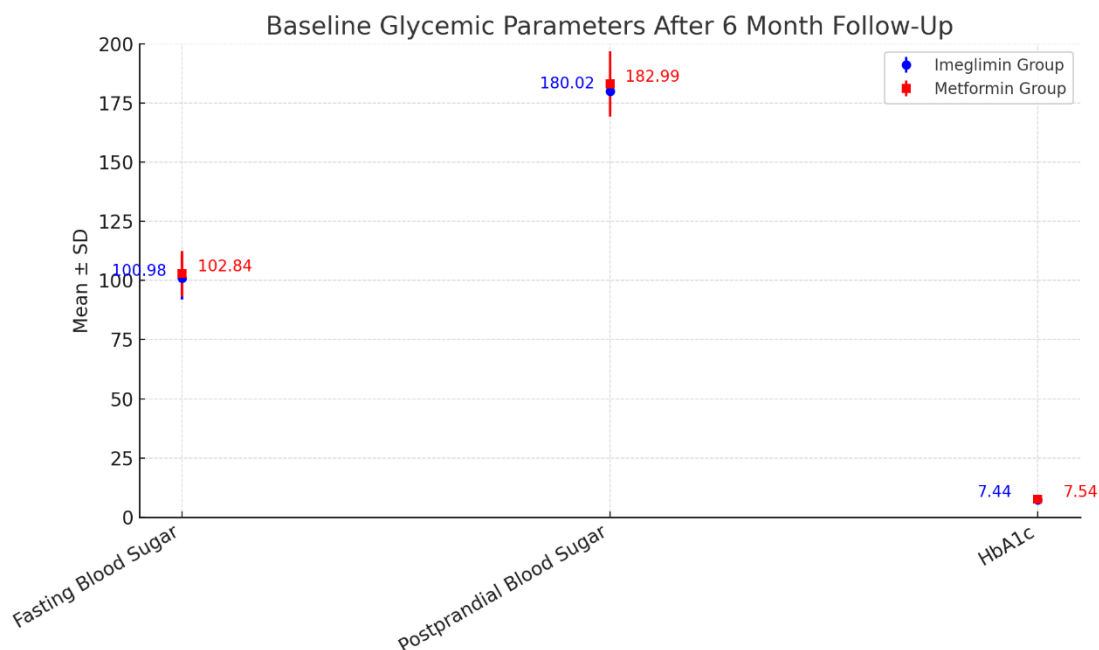


Fig 3 shown at the 24 weeks follow-up, both groups showed further improvements in glycemic control, with fasting blood sugar, postprandial blood sugar, and HbA1c showing no statistically significant differences

between Imeglimin and Metformin groups (P = 0.182, 0.091, and 0.305, respectively this indicates that efficacy of both Imeglimin and Metformin Is equal in terms of achieving glycemic control.

Table 2: Distribution of Lipid Profile Changes After Follow-Up among study participants (n=180)

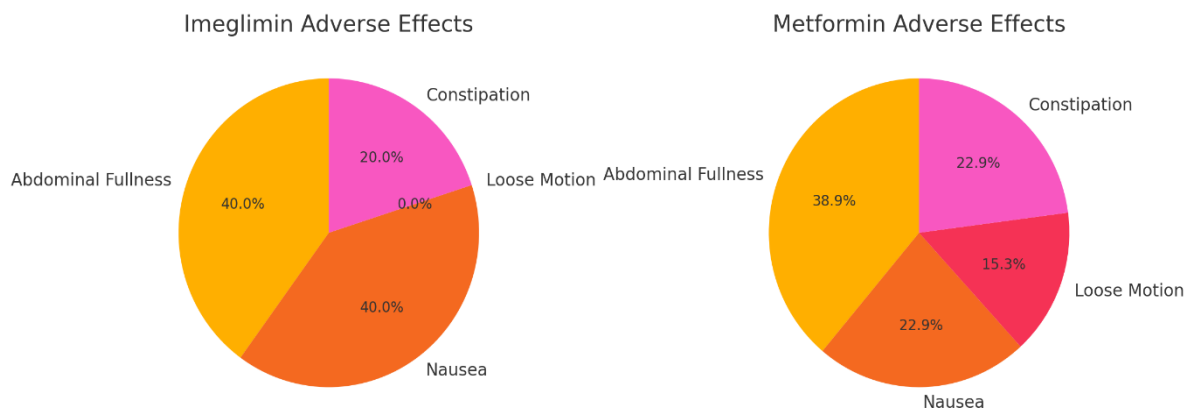
Variable	Imeglimin Group (n=90)	Metformin Group (n=90)	P Value
Lipid profile TC	166.5 ± 16.6	167.9 ± 16.71	0.574
TG	180.0 ± 15.72	182.1 ± 17.77	0.402
LDL	92.1 ± 9.82	91.1 ± 10.28	0.505
HDL	39.5 ± 5.52	41.7 ± 5.48	0.008

Table 2 shows that, in terms of changes to lipid profile after follow-up, both groups experienced reductions in total cholesterol (TC), triglycerides (TG), and LDL, with no statistically significant differences between the groups (P = 0.574, 0.402, and 0.505, respectively). However, the Metformin group showed a significantly higher increase in HDL (41.7 ± 5.48) compared to the Imeglimin group (39.5 ± 5.52) (P = 0.008), indicating a potential cardiovascular benefit. This added benefit may be analysed in the future with a comparative study with a large sample size.

Adverse events were mainly related to gastrointestinal intolerance. The most frequently reported adverse reaction was abdominal fullness, occurring in 2 participants (2.2%) in the Imeglimin group and 5

participants (5.6%) in the Metformin group. Other adverse events, including nausea occurring in 2 participants (2.2%) in the Imeglimin group and 3 (3.3%) participants in Metformin group, loose motion occurring in no participants in the Imeglimin group and 2 participants (2.2%) in Metformin group, and constipation occurring in 1 participant (1.1%) in the Imeglimin group and 3 (3.3%) participants in Metformin group were reported infrequently, with no statistically significant differences observed between the two treatment groups for any adverse reaction. Hypoglycemia (symptomatic/asymptomatic) was not observed in either group in any patients during the study. There was no QT prolongation in any study group.

Fig 4: Adverse Drug Reactions During the Study of the participant (N=180)



In summary, this study demonstrates that Imeglimin provides comparable glycaemic control to Metformin over a period of 24 weeks, with similar safety and better gastrointestinal tolerability. While Metformin showed a slight advantage in raising HDL levels, the overall lipid profile improvements were similar between the two groups. These results suggest that Imeglimin can serve as an effective and well-tolerated alternative to Metformin in the management of type 2 diabetes.

Discussion:

Imeglimin is a novel oral hypoglycemic agent (OHA) belonging to a newly identified drug class called "glimins," characterized by the presence of a tetrahydrotriazine ring and a structural resemblance to metformin.⁵ This compound plays a unique role in diabetes management by stimulating the production of NAD⁺ through the activation of nicotinamide phosphoribosyltransferase (NAMPT). As a result, mitochondrial efficiency is enhanced, and intracellular calcium levels are regulated, both of which are essential for optimal insulin release. Glimin increases glucose-stimulated insulin secretion (GSIS) and preserves pancreatic β-cell mass, thereby boosting insulin secretion.⁶ They also improve insulin action by decreasing hepatic glucose production and correcting disrupted insulin pathways in both liver and skeletal muscle cells.⁷ Imeglimin has been shown to benefit three key pathogenetic elements of type 2 diabetes (T2D)⁶: increased gluconeogenesis, inadequate glucose-induced insulin secretion by beta cells, and peripheral insulin resistance.⁸ Whereas both Metformin and Imeglimin target mitochondrial complex I, their therapeutic actions differ due to their different biochemical profiles. Imeglimin also provides added advantages, such as better gastrointestinal tolerance, and a reduced likelihood of lactic acidosis, making it a valuable option for patients who are unable to tolerate Metformin.⁵ Serum lactate levels were not routinely monitored during the study. However, patients were assessed clinically for any signs and symptoms suggestive of lactic acidosis such as unexplained fatigue, muscle pain, abdominal discomfort, or respiratory distress. Participants with known risk factors for lactic acidosis—such as renal impairment, liver dysfunction, or conditions predisposing to hypoxia were either excluded

from the study or closely monitored as per standard safety protocols.

Naive type 2 diabetes mellitus patients not on any medications were included in this study. The study aim was to compare the efficacy and safety of Imeglimin and Metformin on different parameters. Both groups were observed for clinically significant decreases in FBS, PPBS, and HbA1c in Imeglimin treatment compared to Metformin. Our findings indicate that Imeglimin led to a 34.47% reduction in FBS, while Metformin resulted in a 33.96% reduction over 180 days, demonstrating comparable efficacy between the two drugs. Imeglimin reduced PPBS by 22.81%, whereas Metformin reduced it by 23.17%, indicating nearly identical outcomes. A reduction in HbA1c levels was also observed, with Imeglimin achieving a 0.98% decrease and metformin a 1.00% decrease, further supporting their similar effectiveness. No significant difference between the means of both groups was found.

Compared to other studies, where Pirag et al.⁹ (2012) and Pacini et al.¹⁰ (2015) suggest that Imeglimin is more effective than Metformin, in contrast, a study done by Pirags et al.³⁵ (2021) indicates that Imeglimin BID resulted in the greatest reduction in plasma glucose concentration from baseline, followed by Metformin, while once-daily dosing of Imeglimin demonstrated similar efficacy to Metformin.

In addition to glycemic control, our study also examined lipid profile changes. Imeglimin led to a 13.78% reduction in total cholesterol (TC) and a 15.29% decrease in triglycerides (TGs), while Metformin showed a 12.93% and 14.94% reduction, respectively, indicating similar efficacy. LDL levels decreased by 14.72% with Imeglimin and 13.26% with Metformin, suggesting both drugs had a comparable impact. Interestingly, Imeglimin increased HDL levels by 27.42%, whereas Metformin increased HDL by 26.95%, showing almost identical effects.

In this study, adverse effects such as nausea, abdominal fullness, constipation, and loose motion were observed. Abdominal fullness and constipation were mostly observed in patients who received Metformin. Similar findings were reported by Pirags et al.⁹, where more gastrointestinal side effects were observed in patients who received Metformin than in those who received Imeglimin. In contrast, Douborgetal et al.¹¹ found that

Imeglimin exhibited more gastrointestinal side effects than Metformin.

Hypoglycemia was not observed with either Imeglimin or Metformin during the study. On analysis of adverse effects in our study, both groups had comparable safety profile. None of the groups had shown any serious unexpected adverse effects or the need to discontinue the treatment.

The primary objective of this study was to evaluate the safety and efficacy of Imeglimin and Metformin in newly diagnosed Indian patients with T2DM. The results indicate that Imeglimin provides nearly the same level of glycemic control as Metformin, making it a promising alternative for managing diabetes.

Strength of the study:

The primary strength of this is that it focused on a well-defined group of recently diagnosed type 2 diabetes (T2DM) patients who have not yet started Metformin or any other medication.

→ This focused approach allowed for a clear evaluation of the effectiveness and safety of the add-on treatments. Additionally, by comparing Metformin and Imeglimin, the study provides useful insights that can help guide clinical decisions.

→ To ensure accurate and comprehensive treatment data, the robust methodology followed by this involves closely monitoring blood sugar levels, HbA1c, and other important biochemical markers.

Limitations of the study:

- The small sample size and participant demographics may limit the study's findings, which makes it difficult to apply the results of this study to a larger population.
- The short-term nature of this study might not reveal long-term impacts or adverse treatment effects. Additionally, variables like nutrition, exercise, and other medical conditions could have an impact on the outcomes, which were not included in this study.
- Adherence to the medications is one of the most important variables in treatment outcome, but it is challenging to monitor precisely.
- To comprehensively understand the advantages and disadvantages of Imeglimin and Metformin, the long-term safety and side effect profile of both drugs have to be evaluated, which might not have been thoroughly evaluated in this study.
- The initial HbA1c levels and how long the participants had diabetes could confound the results. Compared to multicenter studies, which provide diverse data and higher accuracy, this single-center study makes it less reliable.

Conclusion:

This study shows that both Imeglimin and Metformin significantly lower fasting blood sugar (FBS), postprandial blood sugar (PPBS), and HbA1c regardless of the patient's starting HbA1c level. Interestingly,

Imeglimin exhibits comparable safety and efficacy in lowering FBS, PPBS, and HbA1c to Metformin.

The findings of this study have important implications for clinical practice, indicating that both Imeglimin and Metformin can be effective options in managing blood sugar in newly diagnosed type 2 diabetes patients. Additionally, our study showed that both these medications helped improve lipid profile, including lowering triglycerides (TG), total cholesterol (TC), and low-density lipoprotein (LDL) while increasing high-density lipoprotein (HDL).

The safety and efficacy of the drugs need to be taken into account when developing treatment plans for patients with newly diagnosed type 2 diabetes. The long-term safety and efficacy of these drugs require further evaluation, needing further research and extended clinical trials. Ongoing investigations will be key in refining treatment strategies and improving diabetes management.

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