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**Original Research Article**

# GLIMPSE study: exploring the effectiveness of glimepiride and metformin combination therapy in newly diagnosed type 2 diabetes in India

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## ABSTRACT

**Background:** Glimepiride and metformin FDC are still relevant in Indian settings as it promotes beta cell responsiveness, protects them from apoptosis and is highly cost-effective. The study aims to primarily understand the usage pattern of initial combination therapy of metformin and glimepiride in newly diagnosed T2DM patients in India.
**Methods:** A retrospective multi-center cross-sectional study was conducted on 17994 newly diagnosed diabetic patients receiving an FDC of glimepiride and metformin. Baseline data included patient demographics and clinical examination findings, while glycemic parameters were measured at baseline and after 3 months of combination therapy. Key variables assessed included FDC strength, dosage frequency and the rationale for selecting the glimepiride-metformin combination. The clinician's global assessment of therapy safety and effectiveness was also recorded.
**Results:** The most frequently prescribed fixed-dose combinations (FDCs) were glimepiride 2 mg with metformin 500 mg (30.49%) and glimepiride 1 mg with metformin 500 mg (30.15%). Age was a significant determinant in the selection of combination therapy ($p<0.001$). At baseline, the mean hemoglobin A1c (HbA1c) level was 8.3%, which significantly improved to 7.3% following treatment for 3 months ($p<0.001$). Post-treatment FBG levels decreased from 172.8 mg/dl to 134.2 mg/dl, while postprandial blood glucose (PPBG) levels were reduced from 245.9 mg/dl to 187.8 mg/dl (both $p<0.001$). The majority of patients demonstrated either excellent or good outcomes based on the clinician's global assessment of treatment effectiveness and safety.
**Conclusions:** Metformin 500 mg with either 1 mg or 2 mg of glimepiride is the most frequently prescribed FDC in newly diagnosed T2DM patients as it offers mechanistic complementarity for insulin resistance and β-cell dysfunction, with good safety profile, along with cost effectiveness.

**Keywords:** Fixed dose combination, Glimepiride, Glycemic control, Metformin, Type 2 diabetes mellitus

## INTRODUCTION

Diabetes is a clinical condition, with abnormal glucose metabolism due to either impaired synthesis of insulin from the beta-cells or the body's inability to use insulin effectively.[1] The recent decades have observed a substantial surge in the prevalence of diabetes, with a notable shift from rising cases in developed nations to developing countries. Approximately 463 million individuals are affected by diabetes globally, accounting for over 4 million deaths annually.[2] Diabetes poses a significant challenge to the Indian healthcare system, accounting for several macrovascular and microvascular complications. Among the Indian population, 77 million adults are currently diagnosed with type 2 diabetes mellitus (T2DM) and 25 million individuals are categorized as prediabetic.[1,3]

Hence, the number of cases of newly diagnosed diabetic patients is expected to rise, necessitating the development of effective management strategies that can improve patient outcomes from the initiation of therapy. Despite the availability of several pharmacological therapies, glycemic control in India remains suboptimal. A recent

large-scale population-based screening study, the SMART India study, was conducted on patients from 10 states and one union territory. The study demonstrated that around 75% of diabetic patients had inadequate glycemic control with a serum HbA1c level higher than 7% and 40% reported HbA1c levels greater than 9%.[4] These findings highlight the challenges of achieving glycemic targets, potentially due to the limited efficacy of monotherapies, which are widely used as a first-line treatment in India. Supporting this hypothesis, longitudinal data from the UK perspective diabetes study (UKPDS) observed that monotherapies administering oral hypoglycemic agents are ineffective when used over a prolonged period, prompting the introduction of additional drugs later in the disease course to achieve and sustain glycemic targets.[5]

Metformin is used a first-line therapeutic agent, widely accepted for managing diabetes. The addition of modern sulfonylureas, such as glimepiride or gliclazide MR to metformin has emerged as an effective combination therapy for achieving optimal glycemic control. Glimepiride offers enhanced beta-cell function, effective insulin secretion, low cardiovascular risk and a reduced risk of hypoglycemia.[6]

The combination regimen of metformin and glimepiride effectively addresses two major pathophysiological defects in diabetes; impaired insulin secretion and insulin resistance. By using combination therapy, the required doses of individual antidiabetic agents are reduced, mitigating the risk of drug-associated adverse events.[7] The glimepiride-metformin combinations are pre-dominantly prescribed in Indian clinical practice, given their low cost compared to other drugs and documented efficacy in lowering blood glucose levels.[8,9]

There is a consensus among national and international guidelines recommending the administration of fixed-dose combinations (FDCs) comprising two or more antihyperglycemic drugs to improve their safety and efficacy in diabetic patients.[10,11] In India, there is widespread availability of glimepiride-metformin FDCs in multiple dosage strengths, which help in drug titration as per patient requirement and simplify prescribing practices, promoting their acceptance among physicians.[12]

While metformin-glimepiride combinations are typically used after the failure of metformin monotherapy, their use as first-line therapy for newly diagnosed patients lacks clinical evidence. However, an early initiation of the combination therapy can potentially help to achieve sustained glycemic control. This approach may mitigate the adverse consequences of a negative glycemic memory, which typically results in microvascular and macrovascular complications.

Additionally, the use of metformin and glimepiride FDC improves patient adherence and reduces clinical inertia.[13] As the FDC is prescribed at different dose strengths in India, the GLIMPSE study aims to identify the prescribing patterns and use of different strengths of the FDC including metformin and glimepiride in the treatment of newly-diagnosed T2DM patients.[14]

## METHODS

### *Study design and participants*

The GLIMPSE study is a multicenter, retrospective, cross-sectional study, enrolling patients from hospitals, clinics and healthcare institutions in India from May 2024-October 2024. The study included newly diagnosed adult diabetic patients who were prescribed glimepiride and metformin FDC, as per the treating physician's discretion. Patients with incomplete medical records or those receiving antihyperglycemic medications other than the glimepiride-metformin combination were excluded from the study.

### *Data collection*

Data were retrospectively collected from patient medical records by physicians, diabetologists and endocrinologists treating diabetic patients at different participating centers across India. No additional diagnostic tests or investigations were performed to capture study data. The collected information was extracted directly from existing patient health records. Demographic variables that were investigated included patient age, gender, height and weight. Risk factors for diabetes were evaluated such as body mass index (BMI), active smoking, alcohol intake, tobacco use, familial history of diabetes and physical inactivity.

### *Study outcomes*

The primary outcome assessed was the strength and dosage frequency of the metformin-glimepiride FDC in newly diagnosed patients with T2DM. Changes in glycemic parameters such as glycated hemoglobin (HbA1c), fasting blood glucose (FBG) and postprandial blood glucose (PPBG) and patient weight were assessed from baseline and the 3-month follow-up after initiating the combination therapy. Physicians provided a qualitative global assessment of the FDC's safety and effectiveness, using a predefined scale of "excellent," "good," "fair," or "poor."

### *Statistical analysis*

The SPSS software was used to perform statistical tests and analysis. Demographic characteristics and clinical parameters are reported using descriptive statistics. Quantitative variable was summarized using mean and standard deviation (SD) and qualitative variables were reported using frequency and percentages. One-way ANOVA was employed to compare the mean age of patients across groups prescribed different FDC strengths. Paired t-tests were applied to assess changes in HbA1c, FBG, PPBG and body weight from baseline to the 3-month

follow-up. Chi-square tests were used to examine associations between categorical variables, including gender and the selection of combination therapy. A 95% confidence interval (CI) was employed and a p-value<0.05 was considered statistically significant.

### *Ethical considerations*

Ethics committee approval was obtained before initiating the study. The study was conducted in following the Indian Council of Medical Research's (ICMR) "Ethical Guidelines for Biomedical Research on Human Participants." The study posed less than minimal risk to participants, as data were collected retrospectively from existing medical records. Informed consent was waived as the data were anonymized and no additional patient interventions were involved. Strict confidentiality measures were adhered to, ensuring that data access was restricted to authorized personnel only.

## RESULTS

### *Population demographic and baseline characteristics*

The study included a total of 17,994 newly diagnosed T2DM patients. Patient demographic and baseline characteristics are detailed in table 1. Gender distribution showed a predominance of males (64.29%), with females comprising 35.71% of the total participants. The mean age of the study population was 57.14 years (SD: 10.77). The mean height and weight of participants were 162.81 cm (SD: 39.30) and 73.68 kg (SD: 19.45), respectively.

Analysis of BMI classifications revealed that the majority of the participants (40.49%) were within the normal BMI range (18.5–22.9 kg/m²), followed by 33.86% characterized as overweight (23.0–24.9 kg/m²) and 19.28% classified as obese (≥25 kg/m²). The proportion of underweight individuals (<18.5 kg/m²) was the lowest, contributing to 6.38% of the total patients.

Behavioral risk factors for diabetes were prevalent in the study population. Active smoking was reported in 18.61% of participants, alcohol intake in 20.70% and tobacco use in 12.86% of the participants. Physical inactivity was observed in 26.27% of patients, while 42.81% had a familial history of diabetes (Table 1).

### *Patterns in the usage of metformin and glimepiride fixed dose combination*

Among the FDCs of metformin and glimepiride, the most frequently prescribed regimens were glimepiride 2 mg with metformin 500 mg (30.49%) and glimepiride 1 mg with metformin 500 mg (30.15%) (Table 2). Other commonly administered combinations included glimepiride 2 mg with metformin 1000 mg (11.92%) and glimepiride 1 mg with metformin 1000 mg (11.82%). These findings suggest a preference for lower-dose metformin-glimepiride combinations in clinical practice, reflecting efforts to optimize safety and tolerability while achieving glycemic targets.

### *Age and gender correlation with fixed dose combination initiation*

The selection of FDC regimens varied significantly with age (p<0.001) (Table 5). Patients who were prescribed higher doses of glimepiride 3 mg with metformin 1000 mg had a mean age of 59.4 years (SD: 11.0), while those initiated on lower doses, such as glimepiride 0.5 mg with metformin 1000 mg, were younger, with a mean age of 54.0 years (SD: 12.4). Gender also influenced prescribing patterns, with glimepiride 2 mg with metformin 500 mg more frequently prescribed to males (n=3,562) than females (n = 1,925) (Table 6).

### *Effectiveness and safety of combination therapy*

Glycemic parameters improved significantly from baseline to 3 months post-combination therapy (Table 3). At baseline, the mean HbA1c level was 8.3% (SD: 1.1), which significantly improved to 7.3% (SD: 0.9) post-treatment (p<0.001). FBG decreased from 172.8 mg/dL (SD: 42.4) to 134.2 mg/dl (SD: 34.5), while PPBG declined from 245.9 mg/dl (SD: 61.6) to 187.8 mg/dl (SD: 45.2), both with p<0.001. A significant decrease in mean body weight was observed post-treatment, reducing from 73.6 kg (SD: 11.9) to 71.2 kg (SD: 11.4) (p<0.001). The clinician global assessment of effectiveness rated the combination therapy as "excellent" in 50.28% of cases and "good" in 44.93% (Table 4). The clinician global assessment of safety reported similar results, with 50.23% rated as "excellent" and 44.93% as "good.".

**Table 1: Patient demographic and baseline clinical parameters.**

| Parameters | Mean | SD |
|---|---|---|
| **Age (in years)** | 57.14 | 10.77 |
| **Height** | 162.81 | 39.30 |
| **Weight** | 73.68 | 19.45 |
| **Gender** | **N** | **%** |
| Male | 11569 | 64.29 |
| Female | 6425 | 35.71 |
| **BMI class** | | |
| Normal BMI (18.5–22.9 kg/m2) | 7285 | 40.49 |

Continued.

| Parameters | Mean | SD |
|---|---|---|
| Overweight (23.0 –24.9 kg/m2) | 6092 | 33.86 |
| Obese (≥25 kg/m$^2$) | 3469 | 19.28 |
| Underweight (<18.5 kg/m$^2$) | 1148 | 6.38 |
| **Active smoker** | | |
| Yes | 3349 | 18.61 |
| No | 14645 | 81.39 |
| **Alcohol intake** | | |
| Yes | 3724 | 20.70 |
| No | 14270 | 79.30 |
| **Tobacco use** | | |
| Yes | 2314 | 12.86 |
| No | 15680 | 87.14 |
| **Family history of diabetes** | | |
| Yes | 7704 | 42.81 |
| No | 10290 | 57.19 |
| **Physical inactivity** | | |
| Yes | 4727 | 26.27 |
| No | 13267 | 73.73 |

**Table 2: Rate of prescription of various strengths of metformin and glimepiride FDC among the study population.**

| Strength | N | % |
|---|---|---|
| **Glimepiride 2 mg/ Metformin 500 mg** | 5487 | 30.49 |
| **Glimepiride 2 mg/ Metformin 1000 mg** | 2145 | 11.92 |
| **Glimepiride 1 mg/Metformin 500 mg** | 5425 | 30.15 |
| **Glimepiride 1 mg/Metformin 1000 mg** | 2127 | 11.82 |
| **Glimepiride 1 mg/Metformin 850 mg** | 341 | 1.90 |
| **Glimepiride 3 mg/Metformin 1000 mg** | 628 | 3.49 |
| **Glimepiride 0.5 mg/Metformin 500 mg** | 844 | 4.69 |
| **Glimepiride 2 mg/Metformin 850 mg** | 137 | 0.76 |
| **Glimepiride 0.5 mg/Metformin 1000 mg** | 479 | 2.66 |
| **Glimepiride 4 mg/Metformin 1000 mg** | 280 | 1.56 |
| **Any Other** | 101 | 0.56 |

**Table 3: Baseline level of HbAC, FBG and PPBG and weight in diabetes patients and changes in glycemic indices post combination therapy with metformin and glimepiride.**

| | Time point | Mean | SD | P value [a] |
|---|---|---|---|---|
| **HbA1C (%)** | Baseline | 8.3 | 1.1 | 0.001* |
| | Endpoint | 7.3 | 0.9 | |
| **Fasting blood glucose (mg/dl)** | Baseline | 172.8 | 42.4 | 0.001* |
| | Endpoint | 134.2 | 34.5 | |
| **Post prandial blood glucose (mg/dl)** | Baseline | 245.9 | 61.6 | 0.001* |
| | Endpoint | 187.8 | 45.2 | |
| **Weight (Kg)** | Baseline | 73.6 | 11.9 | 0.001* |
| | Endpoint | 71.2 | 11.4 | |

[a] P value computed using paired t-test at 95% CI, *Statistically significant.

**Table 4: Real-world effectiveness and safety of initial combination therapy with metformin and glimepiride in diabetes patients.**

| Clinician global assessment of effectiveness | N | % |
|---|---|---|
| **Excellent** | 9048 | 50.28 |
| **Good** | 8084 | 44.93 |
| **Fair** | 816 | 4.53 |

Continued.

| Clinician global assessment of effectiveness | N | % |
|---|---|---|
| **Poor** | 46 | 0.26 |
| **Excellent** | 9038 | 50.23 |
| **Good** | 8085 | 44.93 |
| **Fair** | 820 | 4.56 |
| **Poor** | 51 | 0.28 |

**Table 5: Correlation of age with the selection of initial combination therapy of metformin and glimepiride in newly diagnosed T2DM patients.**

| FDC | Age | | P value[a] |
|---|---|---|---|
| | Mean | SD | |
| **Glimepiride 3 mg/Metformin 1000 mg** | 59.4 | 11.0 | 0.001* |
| **Glimepiride 2 mg/Metformin 850 mg** | 59.1 | 9.4 | |
| **Glimepiride 1 mg/Metformin 850 mg** | 58.2 | 11.9 | |
| **Glimepiride 4 mg/Metformin 1000 mg** | 58.1 | 12.0 | |
| **Glimepiride 2 mg/Metformin 1000 mg** | 58.1 | 11.0 | |
| **Glimepiride 1 mg/Metformin 1000 mg** | 57.8 | 10.6 | |
| **Glimepiride 2 mg/Metformin 500 mg** | 57.2 | 12.5 | |
| **Glimepiride 1 mg/Metformin 500 mg** | 56.7 | 10.8 | |
| **Glimepiride 0.5 mg/Metformin 500 mg** | 54.3 | 11.7 | |
| **Glimepiride 0.5 mg/Metformin 1000 mg** | 54.0 | 12.4 | |

[a] P value computed using One-way ANOVA at 95% CI, *Statistically significant.

**Table 6: Correlation of gender with the selection of initial combination therapy of metformin and glimepiride in newly diagnosed T2DM patients.**

| FDC | Gender | | Total |
|---|---|---|---|
| | Female | Male | |
| **Glimepiride 2 mg/Metformin 500 mg** | 1925 | 3562 | 5487 |
| **Glimepiride 2 mg/Metformin 1000 mg** | 696 | 1449 | 2145 |
| **Glimepiride 1 mg/Metformin 500 mg** | 1959 | 3466 | 5425 |
| **Glimepiride 1 mg/Metformin 1000 mg** | 775 | 1352 | 2127 |
| **Glimepiride 1 mg/Metformin 850 mg** | 115 | 226 | 341 |
| **Glimepiride 3 mg/Metformin 1000 mg** | 199 | 429 | 628 |
| **Glimepiride 0.5 mg/Metformin 500 mg** | 385 | 459 | 844 |
| **Glimepiride 2 mg/Metformin 850 mg** | 52 | 85 | 137 |
| **Glimepiride 0.5 mg/Metformin 1000 mg** | 214 | 265 | 479 |
| **Glimepiride 4 mg/Metformin 1000 mg** | 78 | 202 | 280 |

## DISCUSSION

The GLIMPSE study evaluated the prescription patterns and clinical impact of metformin and glimepiride FDCs prescribed for the treatment of newly diagnosed T2DM patients in India. The findings revealed that physicians frequently prescribed lower doses of the FDC, with glimepiride 2 mg/metformin 500 mg and glimepiride 1 mg/metformin 500 mg being the most prevalent prescriptions in India.

An age-related trend in prescription patterns was observed, where younger patients were more likely to receive lower doses, while higher doses were typically used for older patients. The combination therapy demonstrated therapeutic efficacy, as observed by statistically significant reduction in blood glucose parameters, including HbA1c, FBG and PPBG, after a three-month treatment period. Additionally, the clinician-reported global assessments of effectiveness and safety were overwhelmingly positive, with more than 90% of participants receiving ratings of "excellent" or "good." These findings support the therapeutic efficacy of the combination therapy while offering a tolerable safety profile. Metformin belongs to the class biguanide and exerts its therapeutic effects by reducing hepatic glucose synthesis and improving insulin sensitivity.

Conversely, glimepiride is a second-generation sulfonylurea, playing a role in promoting insulin production by the pancreatic β-cells.[15] The synergistic

activity of glimepiride when used as an adjunct to metformin enhances metabolic and cardiovascular outcomes for patients.[16] The combination therapy of glimepiride with metformin has demonstrated superior efficacy in maintaining optimal glucose levels compared to the administration of high-dose metformin alone.[17] Moreover, these benefits are seen at low doses, reducing the risk of adverse effects associated with higher doses.[16] Therefore, this combination therapy is a promising medical intervention for newly diagnosed T2DM patients. The study reported widespread use of low-dose FDC of metformin and glimepiride, particularly metformin 500/1000 mg with glimepiride 1/2 mg. This informs on the safe prescribing patterns among healthcare professionals managing diabetes in India, which is in alignment with previous studies.

A recent Indian retrospective analysis on a small population of 156 patients, conducted by Sheikh et al reported the most commonly prescribed FDC as glimepiride 2 mg/metformin 500 mg followed by glimepiride 2 mg/metformin 1000 mg.[15] Similarly, a low dose of metformin 500 mg combined with glimepiride at a dosage of either 1 mg or 2 mg was widely prescribed across the diabetic population presenting with significant comorbidities and complications in India.[18]

Further supporting this observation, an Indian case-based questionnaire survey observed that approximately 82% of diabetic patients received low doses of glimepiride (1 mg or 2 mg) in combination with varying doses of metformin.[9] However, the study populations in the aforementioned studies differed from the current study in demographics, focusing on chronic and complex diabetic patients, compared to our predominantly newly diagnosed cohort. Nonetheless, this indicates that low doses are used across diverse T2DM populations, likely due to their better safety profile than higher-dosed FDCs.

The availability of a wide range of metformin and glimepiride FDC strengths allows practitioners to tailor doses based on patient characteristics, such as age, comorbid conditions and complications. The use of low-dose FDC during the initiation of pharmacological treatment in newly diagnosed patients indicates a cautious approach of physicians, aiming to maximize glycemic control while minimizing the risk of side effects. This strategy helps balance efficacy and safety, thereby improving tolerability and patient adherence.

The correlation analysis between the different FDCs and age revealed variation in dosing patterns across age groups, with the mean age of those prescribed lower dosage FDCs significantly lower than those receiving higher dosage regimens. This trend suggests that clinicians prescribe higher doses in older patients, potentially due to the higher prevalence of complications, glucose intolerance and insulin resistance observed in this population.[19,20]

However, elderly patients are predisposed to developing kidney and heart-related complications, which may be exacerbated by the administration of high-dose FDCs.[21] Given these risks, it is essential to consider the renal and cardiovascular health of geriatric patients before initiating high-dose combination therapy. A statistically significant decrease in glycemic indices was observed following treatment initiation with metformin and glimepiride FDC. Similar results have been published previously. The combination therapy led to a decrease in HbA1c from 9.03% to 7.27%, FPG from 175.02 mg/dl to 126.39 mg/dl and PPBG from 259.67 mg/dl to 182.12 mg/dl.[15] Kim et al, reported a reduction of 1.2% and 35.7 mg/dl in HbA1c and FBG, respectively. Additionally, the combination therapy demonstrated better glycemic control than metformin uptitration.[17]

The combination therapy also provides higher glycemic control than glimepiride alone as observed by Yu et al. The study found a 7.6% higher reduction of HbA1c levels with glimepiride and metformin combination, than metformin monotherapy.[22] Therefore, the present study findings and existing literature provide robust evidence for the efficacy of combination therapy in achieving glycemic targets. While the combination of glimepiride and metformin demonstrated safety and effectiveness, it also presents as an affordable intervention accessible to most of the patient population in India.[8]

Evidence from a pharmacoeconomic analysis indicates that this combination was more affordable compared to the FDC of metformin and teneligliptin.[23] Furthermore, glimepiride can achieve glycemic targets with comparable efficacy to newer agents like dipeptidyl peptidase-4 inhibitors (DPP4i) and glucagon-like peptide-1 receptor agonists (GLP-1 RAs), but at a significantly lower cost.[24] Therefore, metformin and glimepiride FDC are particularly relevant in the Indian clinical scenario, where a significant percentage of patients belong to low socioeconomic status.

The GLIMPSE study has several limitations. First, its retrospective design may introduce bias due to the selection of physicians who prescribe only a certain dose based on their preference of familiarity with the regimen. Second, the absence of data on adverse events limits the investigation of the complete safety profile of the combination therapy. Third, the study did not account for long-term glycemic control, which is an important parameter informing whether the combination therapy provides sustained effects. Despite these limitations, the present includes a large number of patients treated across multiple centers in India, providing a holistic overview of the metformin and glimepiride FDC usage patterns in India.

## CONCLUSION

In India for T2DM patients, metformin 500 mg with either 1mg or 2mg of glimepiride is the most frequently

prescribed FDC. This combination demonstrates significant efficacy in glycemic control while maintaining a favorable safety profile. However, further large-scale clinical trials are needed to establish standardized guidelines regarding the appropriate patient populations for specific doses, the optimal timing for dose adjustments and identifying subgroups that may exhibit inadequate glycemic control with the combination therapy.

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