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Real-World Evaluation of Glimepiride and Metformin Combination in Indian Type 2 Diabetes Mellitus Patients with High BMI: GREENPATH Study

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Abstract

Introduction: A key component of treating type 2 diabetes mellitus (T2DM), especially in individuals with elevated body mass index (BMI), is maintaining effective glycaemic control. This practical study assesses the effectiveness, safety, and treatment trends of glimepiride and metformin in Indian patients with type 2 diabetes whose BMI is greater than 23 kg/m².
Materials and Methods: From July 2024 to January 2025, 81 locations throughout India participated in this retrospective, observational, multicentre study. Included were 1275 adult T2DM patients with a BMI greater than 23 kg/m² who were treated with glimepiride (3 mg/4 mg) plus metformin (850 mg/1000 mg). Information about comorbidities, treatment plans, adverse events, and glycaemic and lipid parameters was taken from medical records. Descriptive statistics and paired t-tests were used in the statistical analyses to compare the results before and after treatment.
Results: 62.1% of the population was male, and the mean age was 52.2±10.1 years. The average BMI was 28.5±3.36 kg/m². Most were treated for an average of 38.1±28.4 months with Glimepiride 3 mg + Metformin 850 mg (48.1%). Significant decreases were noted in FPG (267.56 to 144.63 mg/dL), PPG (368.56 to 223.96 mg/dL), and HbA1c (8.41% to 7.51%) ($p<0.001$). Significant improvement was also seen in lipid parameters. 12.3% of patients experienced hypoglycaemia; no serious complications were reported. In more than 70% of cases, the physician's global assessment gave the efficacy and tolerability ratings of "Excellent" or "Very Good."
Conclusion: In overweight Indian patients with type 2 diabetes, the Glimepiride + Metformin combination showed notable real-world efficacy and tolerability in enhancing glycaemic and Lipid profiles

Introduction

Obesity is often linked to type 2 diabetes mellitus (T2DM), a chronic, progressive disease that is particularly prevalent in Indians. Despite being the most common first-line treatment, metformin frequently needs to be used in conjunction with other medications to maintain glycaemic control. Because of their complementary mechanisms, metformin and glimepiride, a sulfonylurea with established cardiovascular safety, are frequently taken together.[1,2,8]

The use of sulfonylurea and metformin offers pharmacodynamic synergistic effects. Physicians and endocrinologists in India manage type 2 diabetic patients using this regimen[1,2]. Guidelines for the management of diabetes recommend metformin as first line agent reduces hepatic gluconeogenesis and glycogenolysis, increases liver and peripheral tissue sensitivity to glucose, and lowers Hb1Ac levels[3,4,6,7]. Glimepiride is a sulphonyl urea and cardiovascular safe drug that stimulates insulin release from pancreatic beta-cells and may act via extra pancreatic mechanisms[5,8].

In India, glimepiride and metformin are frequently used together, especially for patients whose BMI is greater than 23 kg/m² [5]. Despite its widespread use, there is still a lack of empirical data regarding its efficacy, safety, and treatment trends. In line with standard clinical practice, the GREENPATH study intends to assess the effects of this combination on weight, BMI, glycaemic and lipid parameters, and overall tolerability in Indian T2DM patients with elevated BMI.

Materials and Methods

Study Design and Population

A retrospective, multicentre, observational study was conducted across 81 clinical sites in India between July 2024 and January 2025 on Glimepiride(3mg/4mg) + Metformin(850/1000mg) in type 2 diabetes mellitus with obesity with inadequate glycaemic control in Indian clinical settings. The study was conducted in approximately 81 sites in India. The data was extracted from health facility records and entered into electronic case report forms (eCRF).

Data related to demographic characteristics, duration of disease, co-morbidities, concomitant medications, lab data of glycaemic control dosage pattern was collected from medical records authenticated by physicians/endocrinologists during routine care.

Medical records from various medical centres treating patients with type 2 diabetes mellitus were selected. Approvals from the treating physicians and independent ethics committee (IEC) or institutional review board (IRB) was obtained. Post approval from the site investigator and IEC/IRB, the comprehensive patient-level information on demographic, clinical, and laboratory variables were collected and entered in paper CRF (case report form). Medication data and co-morbidities were also collected.

This was a retrospective, multicentre observational study.

Participants:

Adults (≥18 years) diagnosed with T2DM and BMI >23 kg/m², treated with Glimepiride (3/4 mg) + Metformin (850/1000 mg) were included. Patients with type 1 diabetes or incomplete data were excluded.

Endpoints

This study was a retrospective analysis of data collection focused on several key aspects related to the patients diagnosed with type 2 diabetes mellitus with a BMI> 23 kg/m^2 and received treatment with glimepiride + metformin combination. The duration of intake of the treatment with glimepiride +metformin was carefully considered, with special attention given to the change in weight and overall BMI.

This comprehensive data collection aimed to capture patient experiences, evaluate glycaemic control parameters, and understand its effect on weight management.

Ethics

This study was conducted in compliance with the principles of the Declaration of Helsinki, and the protocol approved by the Ethics Committee. The sponsor/designee submitted the study protocol including the waiver for Informed Consent to the responsible IEC/IRB for review. Approval by the IEC/IRB was a pre-requisite for

initiation of the study. The sponsor/designee provided the investigator with a copy of the approval letter and a list of the names and occupations of the committee members.

Data was collected from patient's medical records available at hospital/clinics. The data collected was treated as confidential. The results of the study were made available for review by authorised representatives of sponsor and the ethics committees.

Statistical analysis:

Descriptive statistics were used. Paired t-tests assessed pre- and post-treatment changes. A p-value of <0.05 was considered statistically significant.

Results

Demographics and Baseline Characteristics

Among 1275 patients, the mean age was 52.2±10.1 years, with 62.1% males. The average BMI was 28.5±3.36 kg/m² and mean duration of diabetes was 5.9±4.3 years. Common comorbidities included hypertension (71.7%), dyslipidemia (36.7%), and coronary artery disease (16.7%) (Table 1).

Treatment Patterns:

Most patients (84.7%) were prescribed once-daily regimens. Glimepiride 3mg + Metformin 850mg was the most common combination. The mean treatment duration was 38.1±28.4 months (Table 2).

Glycaemic and Metabolic Control:

Post-treatment improvements were statistically significant for HbA1cwhich was reduced from 8.41% to 7.51% ($p<0.001$), FPG reduced from 267.56 to 144.63 mg/dL ($p<0.001$) and PPG reduced from 368.56 to 223.96 mg/dL ($p<0.001$) (Table 3)

Lipid Parameters:

HDL-C increased from 48.06 to 64.07 mg/dL ($p<0.001$), LDL-C decreased from 153.42 to 114.59 mg/dL ($p<0.001$) and Triglycerides decreased from 174.51 to 135.35 mg/dL ($p<0.001$) (Table 3)

Weight and BMI changes:

32.9% had a decrease in BMI, and 39.3% showed weight reduction. Most reductions were modest (<2 kg/m² BMI; 1–2 kg weight) (Table 4).

Safety Profile:

Hypoglycaemia was reported in 12.3%, with no severe or unresolved events. Other adverse events were minimal (0.2%) (Table 5).

Physician Global Evaluation:

Efficacy was rated as "Excellent" in 32.3% and "Very Good" in 42.2% of patients. Tolerability was similarly rated "Excellent" in 31.5% and "Very Good" in 41.8% (Table 5).

Discussion

This study confirms the clinical utility of Glimepiride + Metformin in routine practice among Indian patients with T2DM and elevated BMI. Significant improvements in glycaemic and lipid profiles, along with favorable physician-reported outcomes and minimal adverse events, underline the combination's relevance in the Indian setting. Unlike randomized controlled trials, this real-world data reflects patient diversity, comorbid conditions, and long-term outcomes under typical healthcare delivery scenarios.

Table 1 Subject Demographics and Health Status

Parameter	Statistics	Overall (N=1275)
Age	n	1275
	Mean	52.2
	SD	10.10
	Median	52.0
	Range: min, max	21.0, 87.0
	95% CI	(51.7, 52.8)
	Male	792, (62.1%)
Gender	Female	483, (37.9%)
Height (cms)	n	1275
	Mean	164.1
	SD	7.61
	Median	165.0
	Range: min, max	140.0, 190.0
	95% CI	(163.7, 164.5)
Weight (Kgs)	n	1275
	Mean	76.7
	SD	10.55
	Median	76.0
	Range: min, max	50.0, 102.0
	95% CI	(76.1, 77.2)
BMI (Kg/m^2)	n	1275
	Mean	28.5

Parameter	Statistics	Overall (N=1275)
	SD	3.36
	Median	27.9
	Range: min, max	23.0, 39.1
	95% CI	(28.3, 28.6)

Table 2: Treatment Patterns

Parameter	Statistics	Overall (N=1275)
Duration of Diabetics (years)	n	1275
	Mean	5.9
	SD	4.34
	Median	5.0
	Range: min, max	1.0, 29.0
	95% CI	(5.7, 6.2)
Treatment Frequency	OD	1080, (84.7%)
	BD	195, (15.3%)
	3mg+1000mg	317, (24.9%)
Treatment Dose (months)	3mg+850mg	613, (48.1%)
	4mg+1000mg	325, (25.5%)
	4mg+850mg	20, (1.6%)
Treatment Duration (months)	n	1275
	Mean	38.1
	SD	28.44
	Median	36.0
	Range: min, max	1.0, 240.0
	95% CI	(36.6, 39.7)

Table 3: Glycaemic Metabolic Control and Lipid Parameters

Parameter	Statistics	Before (N=1275)	After (N=1275)
FPG (mg/dL)	N	1275	1275
	Mean	267.56	144.63
	SD	61.45	36.19
	Median	265.5	134
	Range: min, max	120, 389	96, 240
	95% CI	(264.18, 270.93)	(142.64, 146.62)
	p-value between visits		<0.001
HDL-C (mg/dL)	N	1275	1275
	Mean	48.06	64.07
	SD	9.69	9.81
	Median	46	70
	Range: min, max	30, 78	34, 87
	95% CI	(47.53, 48.59)	(63.53, 64.61)
	p-value between visits		<0.001
HbA1c (%)	N	1275	1275
	Mean	8.41	7.51
	SD	2.23	1.51
	Median	9.0	7.5
	Range: min, max	5.0, 12.6	4.3, 10.4
	95% CI	(8.29, 8.53)	(7.42, 7.59)
	p-value between visits		<0.001
LDL-C (mg/dL)	N	1275	1275
	Mean	153.42	114.59
	SD	10.13	11.67
	Median	156	111
	Range: min, max	123,176	96, 145
	95% CI	(152.86, 153.97)	(113.95, 115.23)
	p-value between visits		<0.001

Parameter	Statistics	Before (N=1275)	After (N=1275)
Non HDL-C (mg/dL)	N	1275	1275
	Mean	195.84	154.29
	SD	56.44	46.01
	Median	204	168
	Range: min, max	44,	32,
	95% CI	(192.74, 198.95)	(151.19, 157.39)
	p-value between visits		<0.001
PPG (mg/dL)	N	1275	1275
	Mean	368.56	223.96
	SD	50.63	12.56
	Median	366	226.5
	Range: min, max	254, 470	202, 245
	95% CI	(365.77, 371.34)	(223.27, 224.65)
	p-value between visits		<0.001
Triglycerides (mg/dL)	N	1275	1275
	Mean	174.51	135.35
	SD	26.02	15.47
	Median	170	137
	Range: min, max	130, 204	110, 167
	95% CI	(173.08, 175.94)	(134.50, 136.20)
	p-value between visits		<0.001

Table 4: Weight and BMI

Parameter	Statistics	Overall (N=1275)
Has patients BMI change during the study	No	855, (67.1%)
	Yes	420, (32.9%)
Decrease in BMI (kg/m^2)	2-4	117, (9.2%)
	< 2	167, (13.1%)
	> 4	2, (0.2%)
Increase in BMI (kg/m^2)	2-4	48, (3.8%)
	< 2	84, (6.6%)
	> 4	2, (0.2%)
Has patients weight change during the study	No	774, (60.7%)
	Yes	501, (39.3%)
Decrease in weight (kg)	1-2	208, (16.3%)
	3-4	28, (2.2%)
	5-6	5, (0.4%)
	< 1	93, (7.3%)
	> 6	1, (0.1%)
Increase in weight (kg)	1-2	69, (5.4%)
	3-4	30, (2.4%)
	5-6	1, (0.1%)
	< 1	65, (5.1%)
	> 6	1, (0.1%)

Table 5: Safety Profile and Physician Global Evaluation of Efficacy and Tolerability

Parameter	Statistics	Overall (N=1275)
Did the patient experience any other Adverse Event	No	1273, (99.8%)
	Yes	2, (0.2%)
If yes, please specify	Vertigo	2, (0.2%)
	Fair	9, (0.7%)
Physician Global Evaluation of Efficacy	Average	51, (4.0%)
	Good	265, (20.8%)
	Very Good	538, (42.2%)
	Excellent	412, (32.3%)
	Fair	9, (0.7%)
	Average	58, (4.5%)
Physician Global Evaluation of Tolerability	Good	274, (21.5%)
	Very Good	533, (41.8%)
	Excellent	401, (31.5%)

Conclusion

The combination therapy of Glimepiride and Metformin is effective, safe, and well-tolerated in managing T2DM patients with BMI >23 kg/m². This study supports its continued use in real-world Indian practice, providing a cost-effective option with favorable outcomes on both glycaemic and metabolic parameters.

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Conflict of Interest

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