REVIEW ARTICLE

Effectiveness of Glimepiride and Metformin in Managing Long-Term Type 2 Diabetes in the Indian Population

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) is increasingly prevalent and associated with increased risk for cardiovascular and renal disease. Therefore, right selection of antidiabetic medications is one of the important tools for managing cardiovascular disease in people with diabetes. American Diabetes Association (ADA) recommends use of combination therapy for better management of T2DM. **Objective:** The purpose of this study was to elucidate the effectiveness of glimepiride and metformin in long-duration T2DM, with or without other oral hypoglycemic agents (OHAs), in the Indian setting. **Material and methods:** A retrospective, multicenter, observational, case-based questionnaire survey was conducted at multiple health care facilities in India using the medical records of T2DM patients who were prescribed various glimepiride/metformin strengths. **Results:** This retrospective observational questionnaire-based analysis comprised 5,097 T2DM patients in total. The mean (±SD) age of patients having diabetes for ≤10 years and >10 years are 51.6 ± 11.54 and 59.75 ± 12.47 years, with BMI 28.47 ± 4.64, and 29.35 ± 5.05 kg/m^2, respectively. The majority (66.54%) of patients came from the less affluent category. Combination of glimepiride/metformin was given to about 4,143 patients in various doses as first-line therapy, and 954 additional patients received the combination in various doses as second-line therapy. About 2.8% of the patients (p = 0.001) complained of hypoglycemia. It was observed that combination therapy of glimepiride and metformin was significantly effective in achieving glycemic control among patients with T2DM for long duration. The study also showed that the drug combination was found to be effective in 95.4% (p = 0.001) patients and well-tolerated in 95.05% (p = 0.001) patients, hence the combination was rated by physicians as good to excellent. **Conclusion:** This study demonstrates the effectiveness of glimepiride and metformin, both individually and in combination with other OHAs. In Indian patients with T2DM, the combination of glimepiride and metformin resulted in satisfactory glycemic control and was well-tolerated.

Keywords: Type 2 diabetes mellitus, ADA, glimepiride/metformin

Introduction

Diabetes is a chronic condition resulting from either inadequate insulin production by the pancreas or impaired insulin utilization by the body. While insulin resistance can arise from various factors, obesity and aging are among the most common contributors[1].

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Type 2 diabetes mellitus (T2DM) is an urgent global threat to the health and well-being of individuals, families, and society as its incidence is on rise globally[2]. According to the International Diabetes Federation (IDF) Diabetes Atlas, 10th edition, 1 in 10 adults, or 537 million people, have diabetes. It is expected that this figure would increase to 643 million by 2030 and 783 million by 2045. Approximately 75% of adults with diabetes live in underdeveloped or developing countries. In 2021, diabetes was responsible for 6.7 million deaths[3].

The scenario is even more adverse in India, as it continues to take the form of an epidemic leading to disability and fatal complications that are related to an increased financial burden[4].

Long-term diabetes increases the risk of various microvascular and macrovascular diseases in patients. Poor glycemic control further elevates the likelihood of developing macrovascular complications, such as coronary artery disease, peripheral arterial disease, and stroke or transient ischemic attack. Additionally, it raises the risk of microvascular complications, including diabetic nephropathy, neuropathy, and retinopathy[2].

First-line treatment options for diabetes typically include monotherapy, with metformin being a common choice. Other antidiabetic drugs include insulin secretagogues, sulfonylurea (SU) (glimepiride), insulin sensitizers, alpha-glucosidase inhibitors, incretin mimetics, amylin antagonists, and sodium-glucose co-transporter-2 (SGLT2) inhibitors are the main medications used to treat type 2 diabetes. Patients who are unable to accomplish treatment goals with first-line oral hypoglycemic agents (OHAs) are recommended combination therapy[5].

According to the UK Prospective Diabetes Study (UKPDS), glycemic control using a single OHA is likely to be ineffective in the longer duration of disease, thus, unavoidably; many patients will require combination therapy to achieve their target glucose level[6].

Several other global bodies like American Diabetes Association/European Association, International Diabetes Federation (IDF), South Asian Federation of Endocrine Societies (SAFES), and Research Society for the Study of Diabetes in India (RSSDI), World Health Organization (WHO) have recommended the use of modern SUs like glimepiride in T2DM management singly or in combination[7-10].

The combination of SU (glimepiride) and metformin is frequently considered for treating T2DM due to its ability to treat "insulin secretion disorder" and "insulin resistance", respectively. Numerous strengths of the fixed-dose combination (FDC) of glimepiride and metformin are offered and frequently utilized by general practitioners and specialists in India[11].

The current study is aimed to analyze the usage and efficiency of the glimepiride and metformin combination in the management of long duration T2DM.

Material and Methods

Study Design

This was a retrospective, multicenter, observational, case-based questionnaire survey. It was conducted with 534 health care professionals (HCPs) across different centers in India from November 2009 to July 2022.

Study Population

Patients of sexes, aged above 18 years, diagnosed with T2DM who received glimepiride (0.5/1/2/3/4 mg)/ metformin (500/850/1000 mg) in different strengths were recruited in the study. About 4,143 patients (3,878 patients with diabetes duration ≤10 years and 265 patients with diabetes duration >10 years) received different strengths of glimepiride/metformin as first-line therapy and 954 patients (741 patients with diabetes duration ≤10 years and 213 patients with diabetes duration >10 years) received different strengths of glimepiride/metformin as second-line therapy (Table 1).

Data Collection

A case report format was developed to determine the pattern of use of different strengths of glimepiride/ metformin FDCs with or without other OHAs in diabetes patients. The questionnaire was sent to 534 HCPs across India via an online portal. Questions regarding demographic characteristics, such as age, sex, body mass index (BMI), weight change, and economic class; duration of diabetes; antidiabetic drugs used

Table 1. Patient Demographics and Treatment

	Diabetes duration		P value
	≤10	>10	
Patient age	51.6 ± 11.54	59.75 ± 12.47	<0.001
Patient BMI	28.47 ± 4.64	29.35 ± 5.05	<0.001
Glimepiride/ Metformin first-line therapy	3,878 (93.6)	265 (6.4)	<0.001
Glimepiride/ Metformin second-line therapy	741 (77.67)	213 (22.33)	

(glimepiride/metformin); antidiabetic drug up-titrations and down-titrations; weight change; hypoglycemic episodes, follow-up and adherence to lifestyle, were included in the questionnaire. An online portal was developed where the HCPs filled in the information. A descriptive analysis was performed with the data provided on the portal.

Statistical Analysis

All continuous variables are expressed as mean ± SD or median with the interquartile range per the data distribution. Categorical variables are expressed as numbers and their respective percentage. Differences in binary and ordinal variables between two independent groups were analyzed by the exact Chi-square test. All the reported p-values are two-sided, and p-values <0.05 are considered to indicate statistical significance. All data entries and statistical analyses were performed by using SPSS® Version 23.0 software.

Results

A total of 5,097 patients with T2DM were included in this retrospective observational questionnaire-based analysis. The mean (±SD) age of patients having diabetes ≤10 years and >10 years are 51.6 ± 11.54 and 59.75 ± 12.47 years, respectively. The mean (±SD) BMI of patients having diabetes ≤10 years and >10 years are 28.47 ± 4.64 and 29.35 ± 5.05 kg/m^2, respectively. Most of the patients belonged to the less affluent category (66.54%). Figure 1 summarizes the economic class and annual incomes of patients.

Four thousand three hundred thirty-four patients (85.03%) found the drug combination available all the time (100%), and 649 (12.73%) found it available 75% of the time. The rest of the patient population found it available <25% of the time.

Dose titration was prevalent in patients receiving glimepiride/metformin as first-line therapy (Fig. 2).

Up-titration was done in 1,678 patients (40.5%) while down-titration was done in 285 patients (6.88%). Up-titration and down-titration in patients receiving other OHAs along with glimepiride/metformin were 310 (32.49%) and 30 (3.14%), respectively.

Physician evaluation of efficacy and tolerability were reported as good to excellent for 95.4% ($p < 0.001$) and 95.05% ($p < 0.001$) patients, respectively (Fig. 3). The main efficacy outcomes were changes in fasting blood glucose (FBG), postprandial plasma glucose (PPG), glycated hemoglobin (HbA1c), and body weight. FBG decreased from 181 mg/dL to 137.5 mg/dL

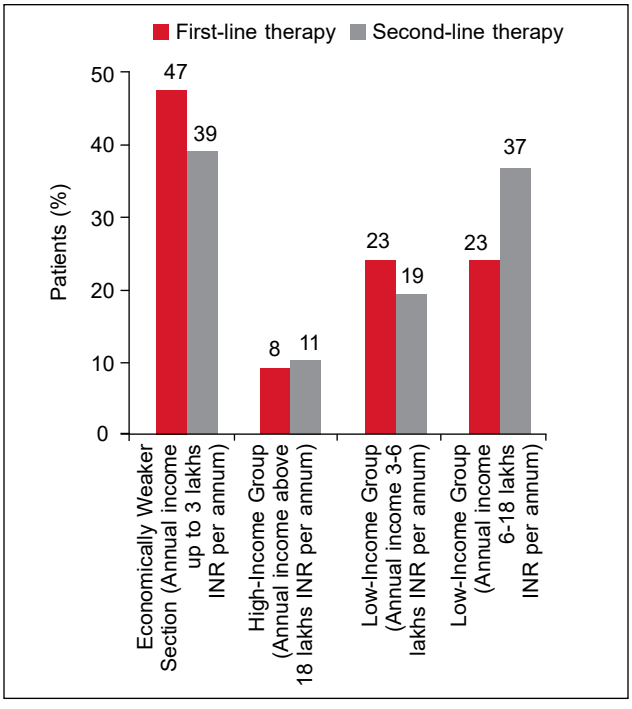

Figure 1. Economic class and annual incomes of patients.

on an average, while PPG lowered from 288.73 mg/dL to 220.97 mg/dL (Fig 4).

A significant ($p = 0.0423$) reduction in the HbA1c value from 8.39% to 6.489% was observed (Fig 5). Weight loss was evident in most patients (63.36%) (Fig. 6).

In this case-based questionnaire survey, out of 5,097 patients, only 154 patients experienced a hypoglycemic event (in the last 6 months) ($p < 0.002$). It was observed that 87.93% patients in the first-line therapy and 63% patients in the second-line therapy adhered to follow ups with doctors as per the advice given. Additionally, the majority of the patients (89.89%) in the first-line therapy and 89.1% patients in the second-line therapy adhered to a healthy lifestyle.

Discussion

Metformin increases insulin sensitivity, while glimepiride increases beta-cell glucose sensitivity and promotes endogenous insulin production. A complementary mechanism of action between glimepiride and metformin results in a considerable decrease in glycemic indices (FPG, PPG, and HbA1c levels). When compared to older generation SUs, Glimepiride a newer SU offers a number of benefits, including enhanced beta-cell activity, weight-neutral effects, absence of cardiovascular risk, and reduced hypoglycemia episodes[12-16]. This study analyzed the use of a glimepiride and metformin combination in Indian patients with

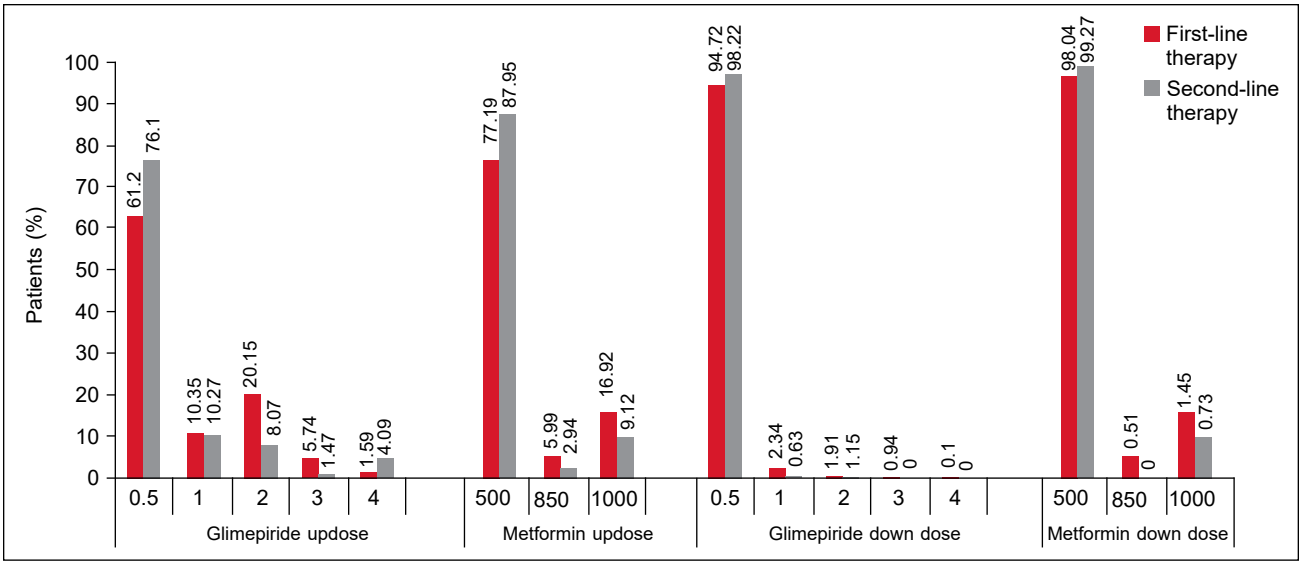

Figure 2. Dose titration of metformin and glimepiride in study patients.

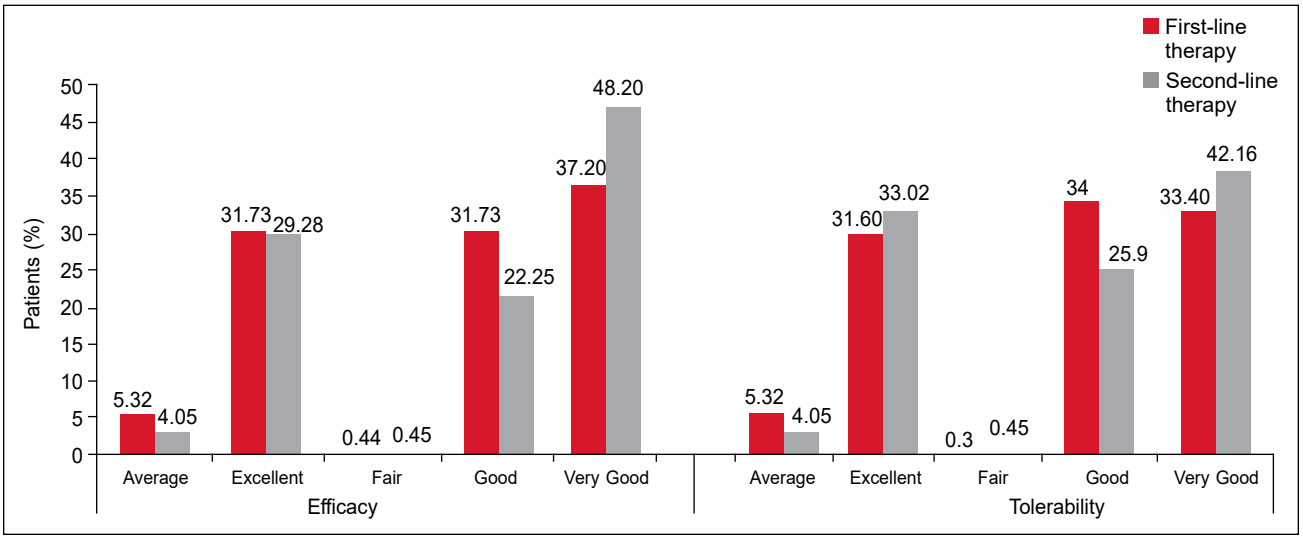

Figure 3. Treatment efficacy and tolerability rating in study patients.

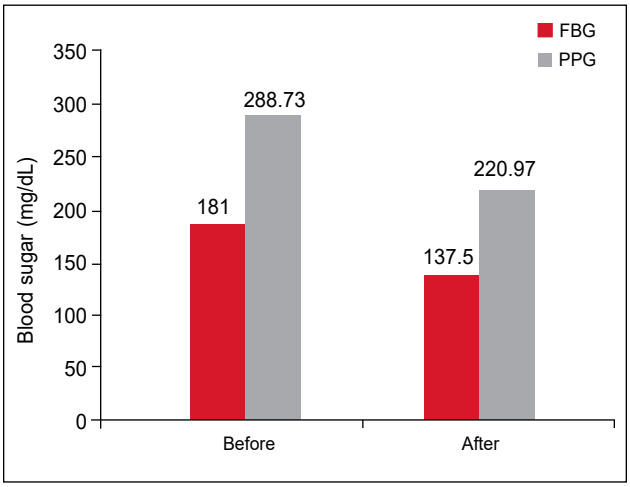

Figure 4. Change in mean FPG and PPG in study patients.

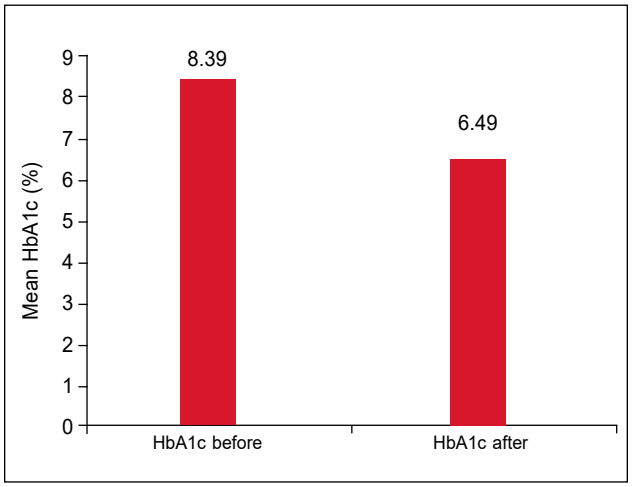

Figure 5. Change in mean HbA1c in study patients.

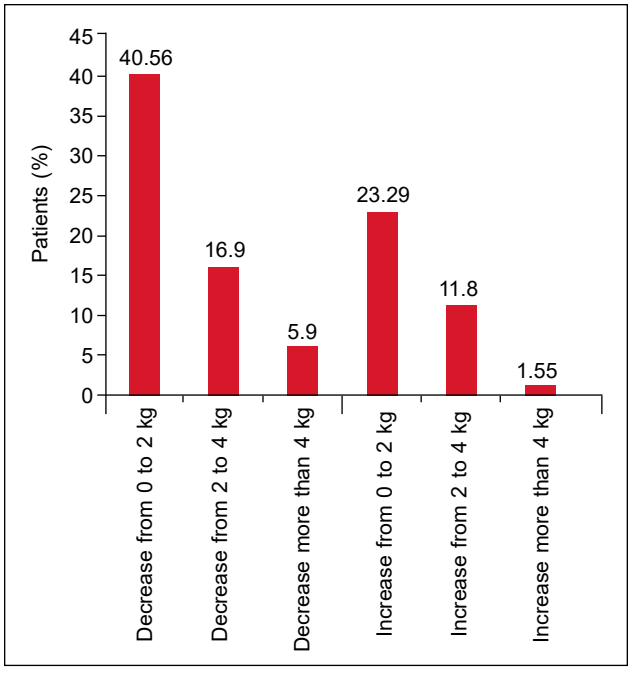

Figure 6. Weight change in study patients.

long-standing T2DM. It included two groups of long-term diabetic patients: those with duration of diabetes <10 years, and those with duration of diabetes of ≥10 years.

Detailed effects of the drug combination on different parameters such as FBG, PPG, HbA1c, and body weight are included. It further highlights the physicians' opinion regarding the efficacy and tolerability of the combination drug.

A study by Nybäck-Nakell et al (2014) demonstrated that SUs may lose their effectiveness over time due to beta-cell exhaustion. However, research has explored the durability of glycemic control achieved through the combination of SUs and metformin in patients with diabetes for both <10 years and ≥10 years[17].

On similar lines, the current study, showed the mean (±SD) age of patients having diabetes ≤10 years and >10 years to be 51.6 ± 11.54 and 59.75 ± 12.47 years, respectively. Four thousand six hundred nineteen patients (90.62%), with a mean age of 51.6 ± 11.54 years, and 478 patients (9.37%), with a mean age of 59.75 ± 12.47 received glimepiride/metformin.

The current results indicate good glycemic control in both the above mentioned categories and showed a sustained legacy effect maintained for a longer duration of diabetes, which was in concordance with the study conducted by Kalra et al[11]. In this study, 4,334 patients (85.03%) found the drug combination available all the time (100%), and 649 (12.73%) found it available 75% of the time. The rest of the patient population found it available <25% of the time. Additionally, the major patient population availing the drug combination belonged to an economically weaker section. Similar observation have been made in different studies which imply that glimepiride/metformin are superior or at least noninferior to other expensive medications, have been used for longer periods of time, and are available in cheap generic formulae which would benefit the huge patient population in India who mostly belong to the less affluent category[18-21].

Dose titration was prevalent in patients receiving glimepiride/metformin as first-line therapy (Fig. 2). Up-titration was done in 1,678 patients (40.5%) while down-titration was done in 285 patients (6.88%). Up-titration and down-titration in patients receiving other OHAs along with glimepiride/metformin were 310 (32.49%) and 30 (3.14%), respectively.

A current case-based questionnaire conducted in Indian patients shows that the glimepiride and metformin combinations are beneficial to T2DM patients irrespective of age, diabetes duration, BMI, and comorbidities from diabetes. These combinations are advantageous, to physicians especially in areas with limited resources due to the simplicity of up- and down-titrations[22].

Physician evaluation of efficacy and tolerability were reported as good to excellent for 95.4% ($p < 0.001$) and 95.05% ($p < 0.001$) patients, respectively (Fig. 3). This is in accordance with the studies shown in a recent retrospective, nonrandomized, noncomparative, multicentric real-world study all the strengths of the glimepiride and metformin combinations are widely prescribed in diabetes with comorbidities like hypertension and dyslipidemia and complications for optimal glycemic control. Glimepiride and metformin FDCs are suitable for early as well as long-term diabetes[4].

Several studies have shown that the addition of glimepiride in T2DM patients uncontrolled by metformin alone resulted in superior glycemic control than metformin monotherapy. Additionally the combined use of glimepiride-metformin in a single presentation was efficacious and safe in patients with T2DM[23-25].

In the current study, a significant decrease in the FBG, PPG, and HbA1c was observed, which is in similar lines with the findings by Phung et al (2010), Hassan and Abd-Allah (2015), Kumar (2021), and Shrivastava et al (2023)[13,26-28].

Our findings found that weight loss was evident in most patients (63.36%) (Fig. 6). Drug combinations containing the modern SU glimepiride + metformin exhibit synergistic activity in terms of glycemic management and superior safety profile by lowering hypoglycemia, weight gain, and cardiovascular profile in comparison to previous generation SUs. Weight loss contributes to improved glycemic control in many obese individuals with diabetes. Hassanein et al (2020) reported comparable weight loss outcomes in the DIA-RAMADAN trial[13,29,30].

This study also reported that only 2.8% of patients ($p < 0.001$) experienced hypoglycemia. The combination of glimepiride/metformin achieves good glycemic control and tolerability. In a recent study, Prasanna Kumar et al also reported a similar finding that stated the efficacy and tolerability to be good to excellent (97.3% and 96.6%) in a vast majority of patients[31]. In another international prospective study, treatment with glimepiride showed fewer hypoglycemic episodes compared to those treated with glibenclamide among patients with diabetes[32].

Glimepiride's documented cardiovascular safety/neutrality and reduced hypoglycemia episodes make it an attractive alternative for the management of persons with long-standing diabetes[33].

Modern SUs offer superior glycemic efficacy, have better cardiovascular profile and are also available at a reasonable cost. Treatment with modern SUs is associated with a lower economic burden, and hence they are an effective alternative to other newer antidiabetic drugs[11].

Treatment decisions are based on glycemic effectiveness and safety profiles, as well as the influence of the therapy on weight and hypoglycemia risk, comorbidities, and treatment costs. The combination of glimepiride and metformin is a viable choice for managing long-term T2DM in developing countries like India.

Conclusion

In conclusion, the study demonstrates that the combination of the SU glimepiride and metformin is a common treatment choice for T2DM. This FDC offers multiple benefits and is widely used by general practitioners and specialists across India.

The current study focuses on evaluating the use and effectiveness of the glimepiride and metformin combination in managing long-term T2DM, providing insights into its role in this patient population. The combination of glimepiride and metformin provided effective glycemic control and was well-tolerated.

Major Findings

- Glimepiride (0.5/1/2/3/4 mg) and metformin (500/850/1000 mg) combinations are widely available in clinical practice.
- In young (<60 years) as well as elderly populations (>60 years) with long-term diabetes (>5 years), glimepiride and metformin combinations are efficacious and well-tolerated.
- The main efficacy outcomes were changes in HbA1c, FBG, PPG, and body weight. There was a significant ($p = 0.0423$) reduction in the HbA1c value. Weight loss was evident in the majority of patients (63.36%).

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