

# Comparative Effectiveness of Tenzeligliptin versus Glimepiride as add on Medications for Patients with Type 2 Diabetes Mellitus with Inadequate Glycemic Control on Metformin

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## INTRODUCTION

- Type 2 Diabetes mellitus (T2DM) is a non-communicable disease of pandemic proportions.
- India fast becoming the 'diabetes capital of world' with ~ 75 million adult patients.
- Metformin failure is common in clinical practice among T2DM patients and requires appropriate add on 2nd line therapy.
- There is a therapeutic dilemma with no clear recommendations regarding choice of add-on drugs for dual therapy, particularly in low income settings.
- Glimepiride among the Sulfonylureas and teneligliptin among the DPP IV inhibitors are two commonly prescribed relatively newer and cheaper drugs in India.
- A head-to-head real world comparison for these two treatment options has not been documented previously.
- Cost is an important factor and barrier in therapeutic decision making in resource limited settings like our government run tertiary care center.
- Real world evidence (RWE) generation through prospective Comparative Effectiveness Research (CER) study is an important tool to address such clinical equipoise.



The estimates in 2021 showed that 74.2 million individuals had diabetes in India, which is expected to rise to over 124.9 million by 2045.

## OBJECTIVES

- To compare the effectiveness of Tenzeligliptin versus Glimepiride as add on therapy in achieving glycaemic control in outpatients with T2DM inadequately controlled on metformin coming to a tertiary care center.
- To compare the safety of these two add on OADs, and their effect on body weight.

## METHODOLOGY

**Study Design:** A Prospective cohort study

**Study Population:** T2DM outpatients coming to the diabetes specialty clinics at AIIMS Bhopal, India

**Data collection:** At baseline, and at least one follow up visit within 6 months

**Proposed sample size:** 45 in each group

Inclusion Criteria	Exclusion Criteria
Adults aged 18-70 years with T2DM	Patients with any other type of diabetes or established ASCVD or HF
Having inadequate glycaemic control (HbA1c $\geq 7\%$ or FBS $\geq 140$ mg/dl) with initial monotherapy with metformin $\geq 1500$ mg or maximally tolerated dose per day for $\geq 12$ weeks	Known absolute / relative contraindications to the use of glimepiride or teneligliptin
Have been prescribed either Glimepiride or Tenzeligliptin as an add on therapy	Patients not showing adequate adherence to medications, diet or lifestyle
Who are willing to participate and give informed consent	Patients with serious mental illness which would affect medication adherence
	Concomitant administration of strong CYP3A4/5 inhibitors or drugs associated with weight gain / loss

## OUTCOME EVALUATION:

- Glycaemic effectiveness was evaluated using HbA1c and FBS, on the basis of change from baseline to follow up, and proportion of patients controlled at follow up visit.
- Safety was assessed on the basis of frequency / proportion of adverse effects.
- Change in body weight was also recorded.

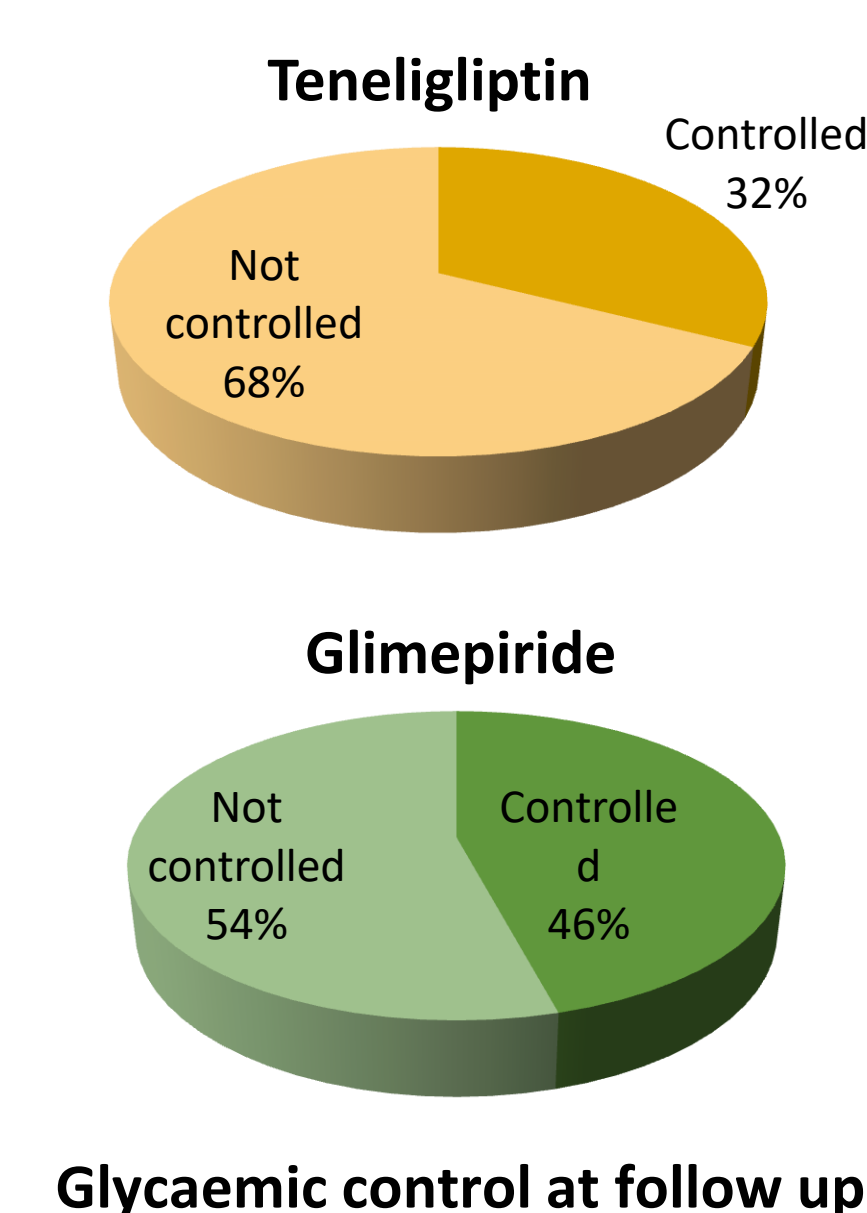
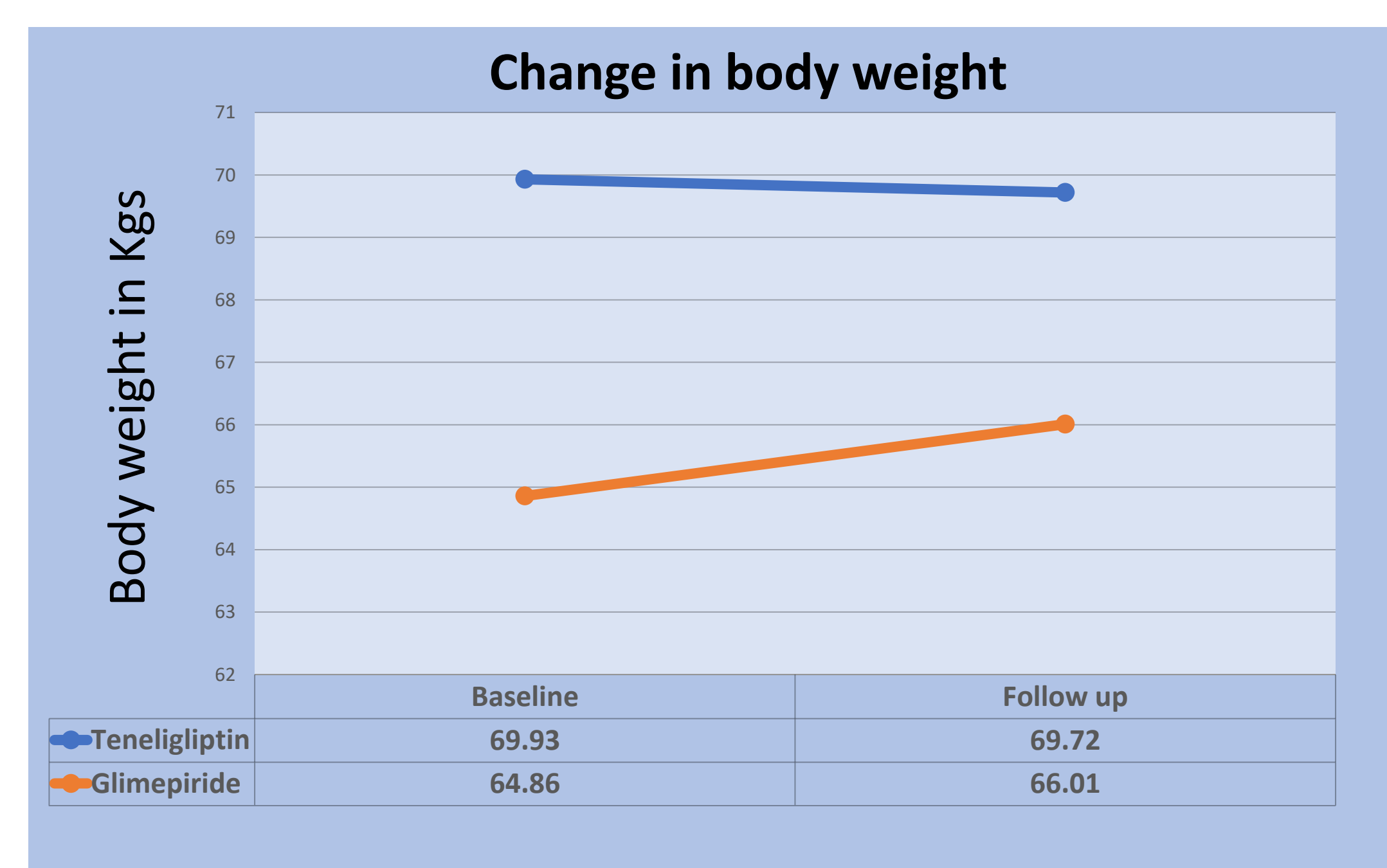
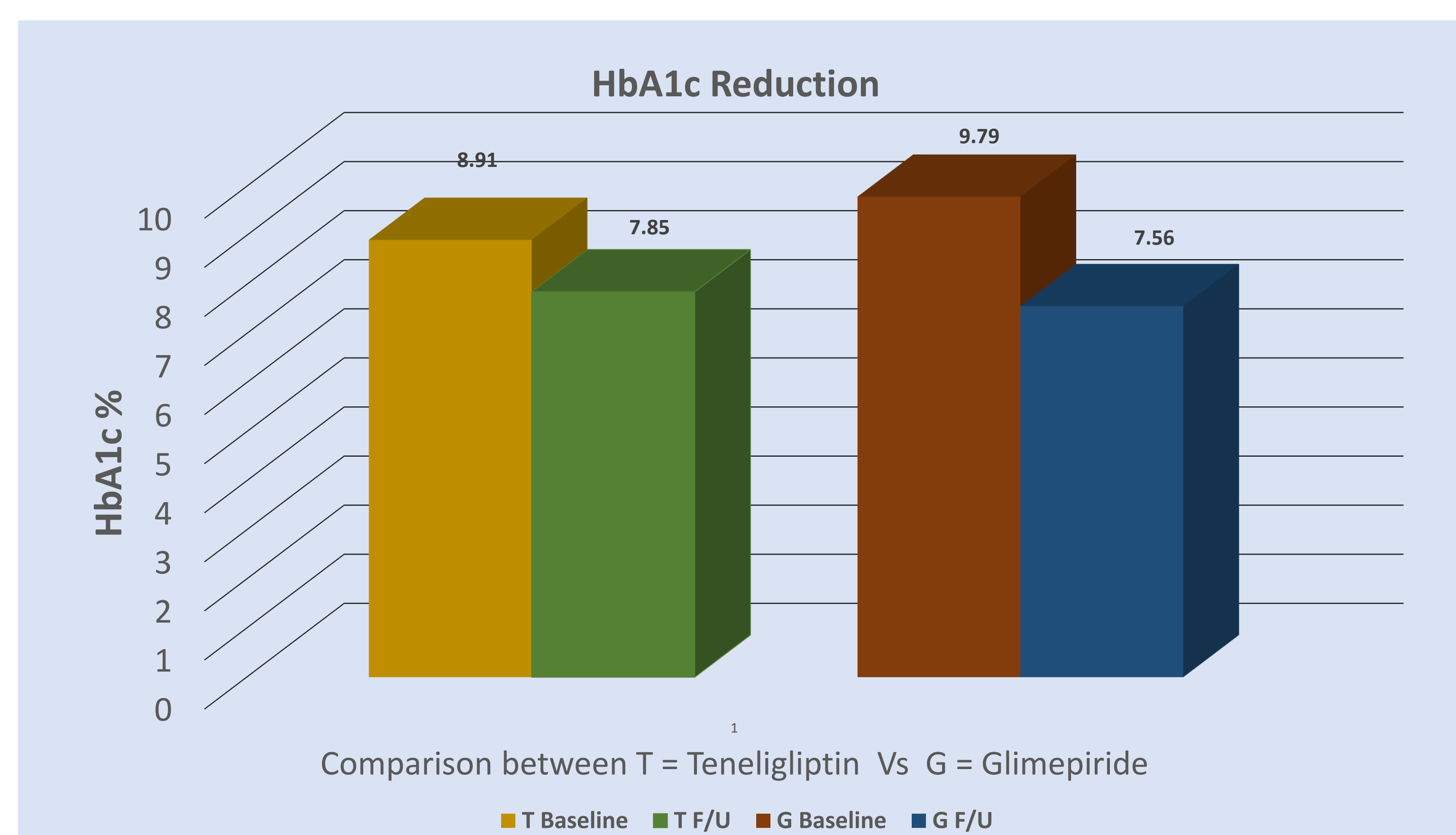
## STASTICAL ANALYSIS

- Data was recorded and analysed using Microsoft Excel version 2021, with calculation of frequencies / proportions, median / mean with standard deviation, and comparison done using t test and chi square test.

## RESULTS

- Data from 64 T2DM patients (58% males, 42% females) was analyzed in this interim analysis.
- Mean reduction in HbA1c in patients receiving glimepiride (n = 24) was  $2.23 \pm 1.62\%$  (p = 0.0003) and  $1.06 \pm 1.36\%$  (p = 0.002) in patients receiving teneligliptin (n = 40).
- HbA1c reduction was quite variable but significantly greater with glimepiride compared to teneligliptin (p = 0.03).
- Mean change in weight was + 1.14 (increase) and - 0.21 kg (decrease) in the glimepiride and teneligliptin groups respectively.
- Similar proportion of patients (15% vs 16%) reported adverse events in both groups.

Baseline Characteristic	Glimepiride (N = 24)	Tenzeligliptin (N = 40)
Age (Years)	50.96 $\pm$ 11.92	51.69 $\pm$ 12.09
Weight (Kgs)	64.86 $\pm$ 10.53	69.93 $\pm$ 8.43
HbA1c (%)	9.79 $\pm$ 1.24	8.91 $\pm$ 1.58
FBS (mg/dl)	249.17 $\pm$ 72.85	192.67 $\pm$ 37.72
Median duration of diagnosed diabetes (IQR, Years)	3 (7.25)	3 (5.5)
Median follow up duration (IQR, months)	4 (7.5)	4 (7)



## CONCLUSION

- Interim results show that glimepiride is a more effective add-on treatment option after metformin with similar safety as compared to teneligliptin.

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