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Original Article

Assessment of Usage of Empagliflozin and Its Combinations in Patients with Newly Diagnosed Type 2 Diabetes

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ABSTRACT

Background and Objectives: Type 2 diabetes mellitus (T2DM) is a rapidly growing public health crisis in India, with over 101 million individuals currently affected. Empagliflozin, a sodium-glucose cotransporter-2 (SGLT-2) inhibitor, has demonstrated compelling benefits in glycaemic control, cardiovascular risk reduction, and renal protection. The EMPIRE (Assessment of Usage of Empagliflozin and Combinations in Patients Newly Diagnosed Type 2 Diabetes) study aimed to evaluate the real-world utilization patterns, clinical effectiveness, and safety of empagliflozin fixed-dose combinations (FDCs) in Indian patients newly diagnosed with T2DM.

Methods: This was an observational, multicentre, non-interventional, real-world evidence study. A total of 15,617 patients with newly diagnosed T2DM who were initiated on empagliflozin-based FDCs were enrolled. Data were collected at baseline and after 3 months of treatment. Primary outcomes included changes in HbA1c, fasting blood glucose (FBG), postprandial blood glucose (PPBG), and body weight. Secondary outcomes encompassed eGFR changes, treatment patterns, concomitant medication use, and clinician-assessed safety and effectiveness.

Results: The study population comprised 15,617 patients (mean age 57.8 ± 11.5 years; 61.7% male). Empagliflozin/Linagliptin FDC was prescribed predominantly at the 25/5 mg dose (57.4%), while the 10/5 mg dose was used in 42.6% of patients. After 3 months, significant reductions were observed in all glycaemic parameters: HbA1c decreased from 8.9 ± 1.4% to 7.4 ± 1.2% ($\Delta = -1.5\%$; $p < 0.001$), FBG from 179.2 ± 51.5 to 136.1 ± 40.6 mg/dL ($\Delta = -43.2$ mg/dL; $p < 0.001$), and PPBG from 256.7 ± 73.1 to 187.2 ± 52.6 mg/dL ($\Delta = -69.5$ mg/dL; $p < 0.001$). Mean body weight decreased by 2.9 ± 4.5 kg ($p < 0.001$). Clinician-assessed safety was rated Excellent or Good in 91.6% of patients, and effectiveness as Excellent or Good in 93.6%. No serious adverse events were reported.

Conclusions: Empagliflozin-based FDCs demonstrated robust glycaemic efficacy, favourable weight reduction, and an excellent safety profile in a large cohort of newly diagnosed T2DM patients in real-world Indian clinical practice. These findings reinforce empagliflozin as an effective and well-tolerated first-line therapeutic option in Indian T2DM management.

Keywords: *Empagliflozin; SGLT-2 inhibitor; Type 2 diabetes mellitus; HbA1c; Real-world evidence; India; Fixed-dose combination; Linagliptin; Metformin.*

INTRODUCTION

Type 2 diabetes mellitus (T2DM) represents one of the most pressing public health challenges globally and particularly in the South Asian region. India has emerged as the diabetes capital of the world, as of 2026, India is estimated to have about 107 million adults living with diabetes, accounting for roughly one-sixth of the global burden. The increasing prevalence of T2DM in India is driven by a confluence of factors including rapid urbanization, sedentary lifestyles, dietary transitions, and genetic predispositions unique to South Asian populations.

The pharmacological management of T2DM has undergone a paradigm shift over the past decade with the introduction of novel glucose-lowering agents that offer benefits beyond glycaemic control. Among these, sodium-glucose cotransporter-2 (SGLT-2) inhibitors have emerged as a transformative class, demonstrating not only effective glycaemic reduction but also proven cardiovascular and renal protective effects in landmark clinical trials.

Empagliflozin is a highly selective SGLT-2 inhibitor approved for the management of T2DM. The pivotal EMPA-REG OUTCOME trial demonstrated a 38% reduction in cardiovascular death, 35% reduction in hospitalization for heart failure, and 39% reduction in renal progression in patients with established cardiovascular disease. The EMPEROR-Reduced and EMPEROR-Preserved trials further established empagliflozin's cardioprotective role, while EMPA-KIDNEY demonstrated its renal benefits in patients with chronic kidney disease (CKD). These data have led to the incorporation of SGLT-2 inhibitors as preferred agents in major international guidelines (*ADA Standards of Care 2024, ESC Guidelines 2023*) and the recently revised RSSDI-ESI Clinical Practice Recommendations for India.

Fixed-dose combinations (FDCs) of empagliflozin with metformin (Empagliflozin/Metformin) and empagliflozin with linagliptin (Empagliflozin/Linagliptin) offer the convenience of combination therapy in a single pill, potentially improving adherence and simplifying treatment regimens. The synergistic mechanisms of SGLT-2 inhibition with DPP-4 inhibition (linagliptin) or with biguanide-mediated insulin sensitization (metformin) provide complementary glycaemic control with a low risk of hypoglycaemia.

Despite the growing body of evidence from large-scale clinical trials, real-world data on the utilization patterns and clinical effectiveness of empagliflozin FDCs in newly diagnosed T2DM patients in India remain limited. The EMPIRE study was designed to address this evidence gap by prospectively collecting real-world data from a large cohort of Indian patients initiating empagliflozin-based therapy in routine clinical practice.

Study Objectives

To evaluate the prescribing patterns of empagliflozin and its fixed-dose combinations (FDCs) in patients with newly diagnosed T2DM in India. To assess the clinical effectiveness of empagliflozin FDCs in terms of changes in HbA1c, fasting blood glucose, postprandial blood glucose, and body weight after 3 months of treatment. To evaluate the safety profile of empagliflozin FDCs, including adverse event reporting and clinician-assessed global safety. To characterize the patient population, including demographics, BMI, comorbidities, and concomitant medications.

METHODS

2.1 Study Design

The EMPIRE study was designed as a retrospective, multicentre, cross-sectional, observational study with data from the last 12 months conducted across multiple clinical centres in India. This study followed the standard clinical practice guidelines without any specific diagnostic or therapeutic interventions. Clinicians enrolled patients based on their routine clinical judgment, and data were collected at two time-points: baseline (at enrolment) and at approximately 3 months after initiation of empagliflozin-based therapy.

2.2 Study Population

Inclusion Criteria

Adult patients (age ≥18 years) with a confirmed diagnosis of type 2 diabetes mellitus who were newly initiated on empagliflozin-based fixed-dose combinations as per the treating physician's clinical judgment, and who provided informed consent for participation, were eligible for inclusion.

Exclusion Criteria

Patients with type 1 diabetes mellitus, known hypersensitivity to empagliflozin or any component of the FDC, eGFR < 30 mL/min/1.73m², pregnancy or lactation, and those currently enrolled in another clinical trial were excluded from the study.

2.3 Data Collection

At enrolment, the following data were collected: patient demographics (age, gender, weight), BMI category (WHO Asian cut-offs for obesity), cardiovascular risk factors (smoking, alcohol use, tobacco use, family history of diabetes, physical inactivity), baseline clinical examination (blood pressure), comorbid conditions, prescribed empagliflozin FDC and dose, and concomitant medications.

Laboratory investigations collected at baseline and 3-month follow-up included: HbA1c (%), fasting blood glucose (FBG, mg/dL), postprandial blood glucose (PPBG, mg/dL), body weight (kg), and estimated glomerular filtration rate (eGFR, mL/min/1.73m²).

2.4 Outcome Measures

Primary Outcomes: Mean change from baseline to 3 months in HbA1c, FBG, PPBG, and body weight.

Secondary Outcomes: Prescription patterns of empagliflozin FDCs (dose and type), concomitant medication usage, change in eGFR, frequency and type of adverse events, and clinician's global assessment of safety and effectiveness.

2.5 Statistical Analysis

All continuous variables are expressed as mean ± standard deviation (SD). Categorical variables are reported as frequencies and percentages. Within-group changes from baseline to 3 months were assessed using paired Student's t-test. A two-tailed p-value of < 0.05 was considered statistically significant. Statistical analyses were performed using Python. Safety and effectiveness outcomes are summarized descriptively.

RESULTS

3.1 Patient Enrolment and Demographics

A total of 15,617 patients with newly diagnosed T2DM were enrolled across multiple clinical centres in India. The mean age of the study population was 57.8 ± 11.5 years (range 18–92 years). The cohort comprised 9,643 males (61.7%) and 5,974 females (38.3%). The demographic and baseline characteristics are summarized in Table 1.

Application of WHO Asian BMI criteria revealed that approximately 41.0% of patients had normal BMI (18.5–22.9 kg/m²), 32.7% were overweight (23.0–24.9 kg/m²), 18.4% were obese (≥25 kg/m²), and 7.9% were underweight (<18.5 kg/m²).

Table 1. Baseline Demographics and Clinical Characteristics (N=15617)

Parameter	Value	Percentage / SD
Age (years)	57.8 ± 11.5	Range: 18–92
Gender		
Male	9,643	61.7%
Female	5,974	38.3%
BMI		
BMI: Normal (18.5–22.9)	6,403	41.0%
BMI: Overweight (23.0–24.9)	5,105	32.7%
BMI: Obese (≥25)	2,870	18.4%
BMI: Underweight (<18.5)	1,239	7.9%
Underlying comorbid condition		
Hypertension	5,501	35.2%
CKD	1,870	12.0%
Heart Failure	1,691	10.8%
Myocardial Infarction	863	5.5%
Stroke/TIA	522	3.3%
Risk factors		
Family History of DM	5,838	37.4%
Physical Inactivity	4,061	26.0%
Active Smoker	2,133	13.7%
Alcohol Use	2,660	17.0%
Tobacco Use	2,355	15.1%

3.2 Empagliflozin Fixed-Dose Combination Prescribing Patterns

Both available FDC formulations of empagliflozin were widely prescribed in this cohort. Empagliflozin/Linagliptin was the most commonly used combination. Among the empagliflozin/linagliptin FDC prescriptions, the 25/5 mg dose was preferred in 57.4% (n=8,958) of patients, while the 10/5 mg dose was prescribed in 42.6% (n=6,659) of patients.

For the empagliflozin/metformin FDC, the distribution of doses was as follows: 5/500 mg was the most commonly prescribed (30.6%, n=4,780), followed by 12.5/500 mg (29.5%, n=4,604), 5/1000 mg (16.4%, n=2,558), and 12.5/1000

mg (15.2%, n=2,375). The remaining 8.3% of patients received alternative formulations or other empagliflozin-containing regimens (Figure 1).

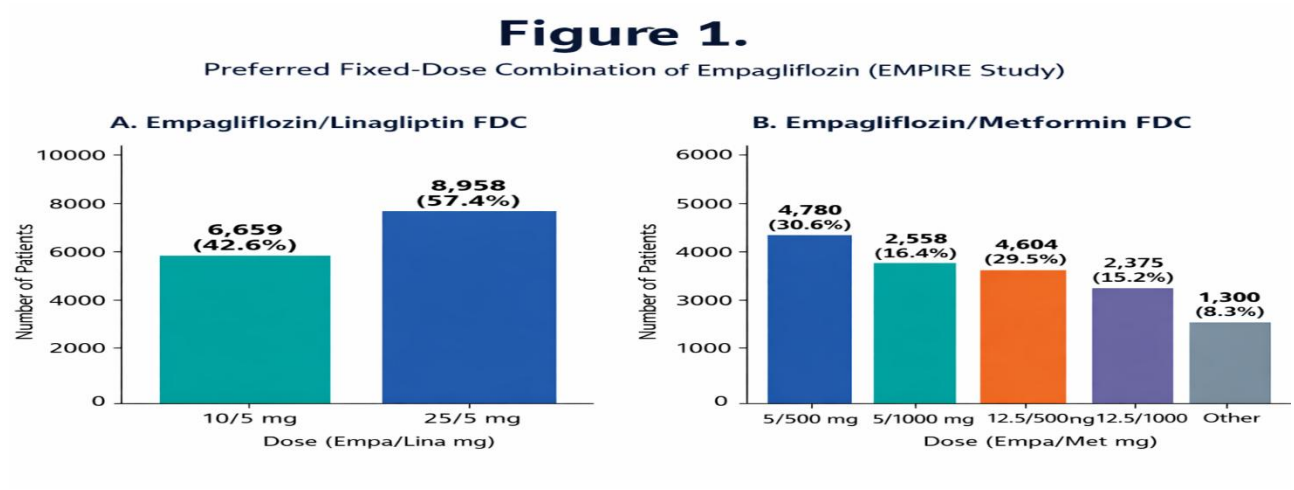

Figure 1. ***Prescribing patterns of empagliflozin fixed-dose combinations. Panel A: Distribution of Empagliflozin/Linagliptin doses; Panel B: Distribution of Empagliflozin/Metformin doses.***

3.3 Concomitant Antidiabetic and Cardiovascular Medications

All empagliflozin prescriptions in this cohort were dispensed as fixed-dose combinations (FDCs). The Empagliflozin/Linagliptin dual FDC was the primary backbone of therapy for all 15,999 patients prescribed at 25/5 mg in 56.2% and at 10/5 mg in 43.8% of cases. An Empagliflozin/Metformin dual FDC was co-prescribed alongside the Empagliflozin/Linagliptin FDC in 94.3% of patients (at 5/500 mg in 32.0%, 12.5/500 mg in 28.9%, 5/1000 mg in 16.1%, and 12.5/1000 mg in 14.9%), effectively delivering a triple antidiabetic combination — empagliflozin + linagliptin + metformin — through the concurrent use of two dual FDCs rather than a single triple-combination tablet. An Empagliflozin/Sitagliptin dual FDC was used in only one recorded instance and was not a meaningful prescribing pattern in this cohort. No single-tablet triple FDCs — such as Empagliflozin/Sitagliptin/Metformin, Empagliflozin/Glimepiride/Metformin, or Empagliflozin/Linagliptin/Metformin — were documented; the triple-agent coverage observed in this dataset was achieved exclusively through co-prescription of two separate dual FDCs.

Over and above this empagliflozin FDC backbone, a wide range of antidiabetic and cardiovascular agents were co-prescribed in combination with empagliflozin. Among antidiabetic agents, glimepiride (sulfonylurea) was co-prescribed alongside empagliflozin FDCs in 89.5% of patients, reflecting its entrenched role in Indian clinical practice. Pioglitazone (thiazolidinedione) was added in 21.5% of patients. Notably, DPP-4 inhibitors were also co-prescribed as supplementary agents on top of the empagliflozin FDC regimen — linagliptin as an additional separate tablet in 18.5%, sitagliptin in 6.2%, and vildagliptin in 1.9% of patients. For cardiovascular risk management, ARBs/ACE inhibitors (19.5%), statins (16.9%), metoprolol (16.8%), diuretics (8.3%), ARNI — sacubitril/valsartan (5.5%), and bisoprolol (2.6%) were co-prescribed alongside the empagliflozin FDC regimen, reflecting the substantial burden of hypertension, dyslipidaemia, and cardiovascular comorbidity in this cohort.

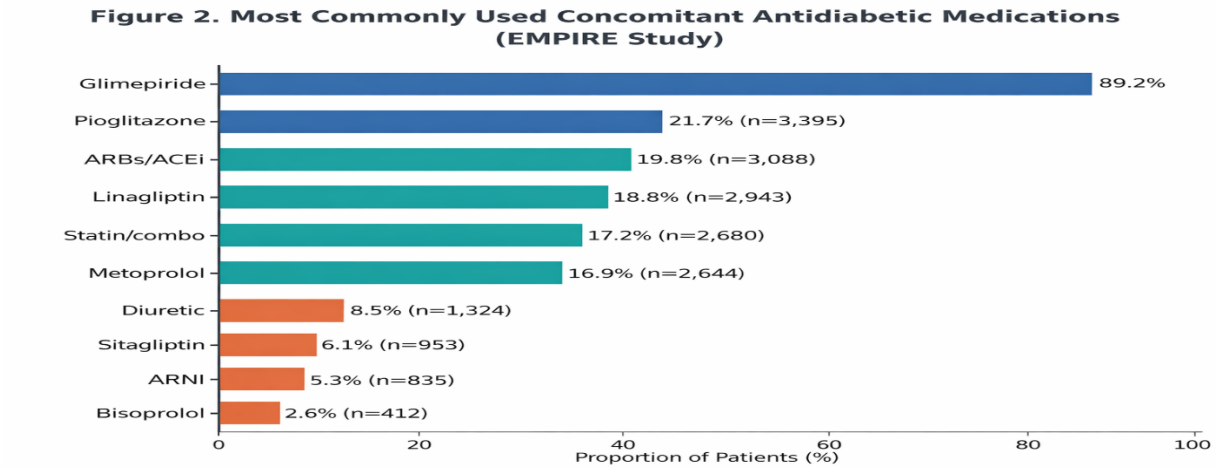

Figure 2. ***Most frequently co-prescribed antidiabetic and cardiovascular medications in patients receiving empagliflozin-based FDCs (EMPIRE Study, N = 15,617).***

3.4 Clinical Efficacy Outcomes

3.4.1 HbA1c Reduction

At baseline, the mean HbA1c was 8.9 ± 1.4%, indicating poor glycaemic control consistent with newly diagnosed, undertreated T2DM. After 3 months of empagliflozin-based therapy, the mean HbA1c decreased significantly to 7.4 ± 1.2%, representing a mean reduction of 1.5 ± 1.1 percentage points ($p < 0.001$; n = 14,146 paired observations). This magnitude of HbA1c reduction is clinically meaningful and comparable to findings reported in randomized controlled trials of empagliflozin.

3.4.2 Fasting and Postprandial Blood Glucose

Fasting blood glucose (FBG) decreased from a baseline of 179.2 ± 51.5 mg/dL to 136.1 ± 40.6 mg/dL at 3 months, representing a mean reduction of 43.2 ± 35.0 mg/dL ($p < 0.001$). Similarly, postprandial blood glucose (PPBG) showed a substantial decline from 256.7 ± 73.1 mg/dL to 187.2 ± 52.6 mg/dL ($\Delta = -69.5 \pm 57.2$ mg/dL; $p < 0.001$). The normalization of PPBG is particularly noteworthy, as postprandial hyperglycaemia is a major risk factor for macrovascular complications in T2DM.

3.4.3 Body Weight

Empagliflozin exerts its glycaemic effects primarily through urinary glucose excretion, which is accompanied by a caloric deficit and consequent weight loss. In this cohort, mean body weight decreased from 74.9 ± 12.2 kg at baseline to 72.0 ± 11.5 kg at 3 months, representing a statistically significant mean reduction of 2.9 ± 4.5 kg ($p < 0.001$). Weight reduction is particularly beneficial in the predominantly overweight/obese Indian T2DM population.

3.4.4 eGFR

The mean eGFR at baseline was 71.6 mL/min/1.73m², indicating predominantly preserved renal function. A modest increase in eGFR was observed at 3 months, consistent with the known Reno protective mechanism of SGLT-2 inhibition through reduction of hyperfiltration. No change in the eGFR changes were observed.

All efficacy outcomes are summarized in Table 2 and Figure 3.

Table 2. Changes in Clinical Parameters from Baseline to 3 Months

Parameter	Baseline	3 Months	Mean Change	p-value
HbA1c (%)	8.9 ± 1.4	7.4 ± 1.2	−1.5 ± 1.1	<0.001
FBG (mg/dL)	179.2 ± 51.5	136.1 ± 40.6	−43.2 ± 35.0	<0.001
PPBG (mg/dL)	256.7 ± 73.1	187.2 ± 52.6	−69.5 ± 57.2	<0.001
Body Weight (kg)	74.9 ± 12.2	72.0 ± 11.5	−2.9 ± 4.5	<0.001
eGFR (mL/min/1.73m²)	71.6 ± 40.1	75.1 ± 184.7	+3.5 ± 182.1	0.017

FBG, fasting blood glucose; PPBG, postprandial blood glucose; eGFR, estimated glomerular filtration rate. Values expressed as Mean ± SD. Paired t-test used for statistical comparison.

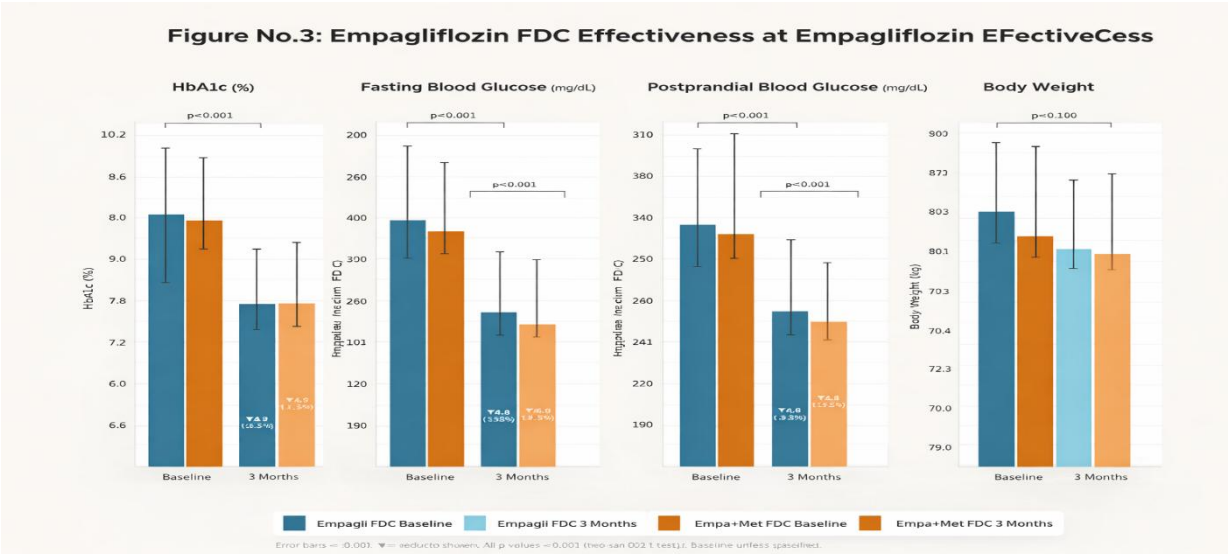

Figure 3. ***Changes in key clinical parameters from baseline to 3 months in patients receiving empagliflozin-based FDCs. All changes were statistically significant (p < 0.001). Error bars represent mean values; orange arrows indicate direction and magnitude of change.***

3.5 Safety and Tolerability

3.5.1 Adverse Events

The overall safety profile of empagliflozin FDCs was excellent in this real-world cohort. No serious adverse events were reported during the 3-month observation period. This is consistent with the well-established safety profile of empagliflozin from clinical trials, which have shown low rates of hypoglycaemia, urinary tract infections, and genital mycotic infections, particularly when SGLT-2 inhibitors are not combined with sulfonylureas or insulin in insulin-secretagogue-naive populations.

3.5.2 Clinician's Global Assessment

At the 3-month follow-up, clinicians assessed the safety of treatment as Excellent in 52.6% (n=8,208) and Good in 39.0% (n=6,094) of patients, with a combined Excellent + Good safety rating of 91.6%. Treatment was rated as Fair in 5.2% and Poor in 3.2% of patients.

For effectiveness, 56.3% (n=8,793) of patients were rated as Excellent and 37.3% (n=5,818) as Good, yielding a combined Excellent + Good effectiveness rating of 93.6%. These high clinician-assessed ratings underscore the real-world clinical utility of empagliflozin FDCs in the management of newly diagnosed T2DM in India. Results are depicted in Figure 4.

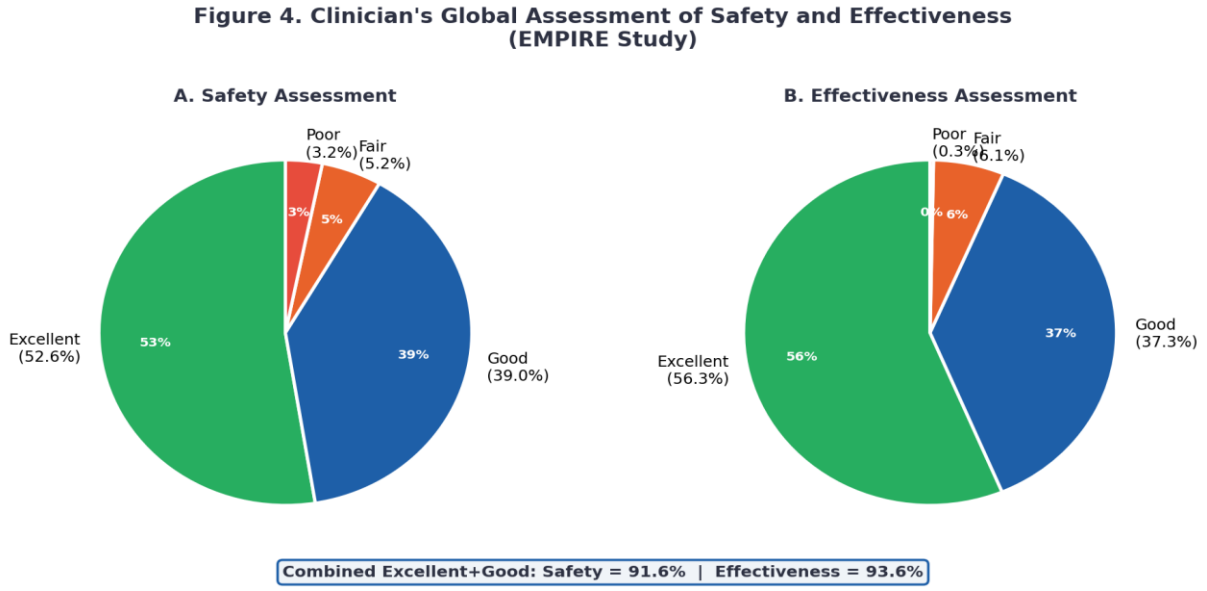

Figure 4. ***Clinician's global assessment of safety and effectiveness at 3-month follow-up. Combined Excellent + Good rating: Safety = 91.6%; Effectiveness = 93.6%.***

DISCUSSION

The EMPIRE study represents one of the largest real-world evidence studies evaluating empagliflozin-based FDCs in patients with newly diagnosed T2DM in India. With 15,617 patients enrolled, this study provides robust data on prescribing patterns, clinical effectiveness, and safety of empagliflozin FDCs in routine clinical practice settings across India.

4.1 Patient Characteristics and Disease Profile

The demographic profile of our cohort is broadly reflective of the Indian T2DM population seen in tertiary and secondary care settings. The mean age of 57.8 years is consistent with the peak incidence of T2DM in India, which tends to occur approximately a decade earlier than in Western populations, highlighting the importance of early and effective glycaemic management to prevent long-term complications.

The high prevalence of hypertension (35.2%) in our cohort underscores the clustering of cardiometabolic risk factors in the Indian T2DM population, where hypertension is the most common coexisting condition. The 10.8% prevalence of heart failure and 12.0% CKD further highlight the need for therapies with proven cardiorenal benefits — a key strength of SGLT-2 inhibitors as a class.

The BMI distribution, assessed using WHO Asian cut-offs, revealed that nearly 50% of patients were overweight or obese (BMI ≥23 kg/m²), consistent with the well-documented trend of increasing adiposity in urban Indian populations. The weight-reducing properties of empagliflozin are particularly relevant in this context.

4.2 Empagliflozin Dose and FDC Selection

The preferential prescribing of the higher empagliflozin dose (25 mg) in the empagliflozin/linagliptin FDC (57.4% of prescriptions) reflects clinicians' awareness of dose-dependent glycaemic and cardiorenal effects. The EMPA-REG OUTCOME and EMPEROR trials enrolled predominantly patients on 10 mg and 25 mg doses, with the 25 mg dose demonstrating numerically greater reductions in HbA1c and glycosuria. For the empagliflozin/metformin FDC, the wide distribution across multiple dose strengths reflects individualized prescribing based on patient tolerability, baseline glycaemic status, and renal function.

The concurrent prescribing of multiple antidiabetic agents, with glimepiride, pioglitazone, and DPP-4 inhibitors being the most common additions, reflects the real-world need for combination therapy to achieve glycaemic targets in newly diagnosed T2DM patients with higher baseline HbA1c values.

4.3 Glycaemic Efficacy

The observed mean HbA1c reduction of 1.5 percentage points from a baseline of 8.9% to 7.4% over 3 months is clinically meaningful and comparable to results from randomized controlled trials. In the EMPA-REG OUTCOME trial, empagliflozin 25 mg reduced HbA1c by approximately 0.5–0.8% as monotherapy in patients on background metformin. The larger reduction observed in our study (−1.5%) likely reflects the additive effect of combination therapy (FDC with linagliptin or metformin) and the higher baseline HbA1c in our newly diagnosed population. The complementary mechanisms of SGLT-2 inhibition (glucose excretion) and DPP-4 inhibition (incretin enhancement) provide synergistic glycaemic benefits.

The substantial reductions in FBG (−43.2 mg/dL) and PPBG (−69.5 mg/dL) observed in our study are clinically significant. The relatively larger reduction in PPBG compared to FBG is consistent with the mechanism of SGLT-2 inhibitors, which reduce glucose reabsorption throughout the day but particularly attenuate postprandial glucose excursions. This dual glycaemic action is advantageous in the Indian population, where postprandial hyperglycaemia is disproportionately prominent.

4.4 Body Weight Reduction

The mean weight loss of **2.9 kg** over 3 months is consistent with clinical trial findings and real-world studies with empagliflozin. Weight reduction with SGLT-2 inhibitors occurs through multiple mechanisms: urinary caloric loss via glucosuria (approximately 200–300 kcal/day), reduction in body fat (particularly visceral adiposity), and osmotic diuresis. In the Indian context, where both overweight/obesity and visceral adiposity are major drivers of insulin resistance, this additional benefit represents a significant advantage of empagliflozin-based therapy over traditional agents such as sulfonylureas, insulin, and thiazolidinediones, which are typically weight-neutral or weight-promoting.

4.5 Safety Profile

The excellent safety profile observed in our cohort — with no serious adverse events reported and 91.6% of patients rated as Excellent or Good for safety — is reassuring and consistent with the established safety data from clinical trials. The low observed rate of adverse events may partially reflect the exclusion of patients with eGFR < 30 mL/min/1.73m², who are at higher risk for volume depletion-related events, and the relatively short 3-month follow-up period.

The high clinician-assessed effectiveness (93.6% rated Excellent or Good) reflects both objective improvements in glycaemic parameters and the overall clinical impression of treatment benefit, including potentially improvements in energy, reduction in polyuria/polydipsia, and cardiovascular risk factor reduction.

4.6 Clinical Implications

The EMPIRE study provides compelling real-world evidence supporting the use of empagliflozin FDCs as effective and well-tolerated first-line or add-on therapy in newly diagnosed T2DM patients in India. The results align with and strengthen the current RSSDI-ESI guideline recommendations that favour SGLT-2 inhibitors in patients with established cardiovascular disease, heart failure, CKD, or obesity — all of which were prevalent in our cohort.

From a health policy perspective, the widespread real-world utilization of empagliflozin FDCs demonstrated in this study, coupled with robust effectiveness and safety outcomes, supports their inclusion in national essential medicines lists and insurance formularies to improve access for Indian patients.

CONCLUSIONS

The EMPIRE study demonstrates that empagliflozin-based fixed-dose combinations are widely prescribed and clinically effective in a large, diverse cohort of newly diagnosed T2DM patients in India. Over a 3-month treatment period, empagliflozin FDCs produced significant reductions in HbA1c (−1.5%), FBG (−43.2 mg/dL), PPBG (−69.5 mg/dL), and body weight (−2.9 kg), all with statistical significance ($p < 0.001$).

The safety profile was favourable, with 91.6% of clinicians rating safety as Excellent or Good and 93.6% rating effectiveness as Excellent or Good. No serious adverse events were reported during the observation period.

These real-world data complement the existing evidence from randomized controlled trials and support the incorporation of empagliflozin FDCs into routine clinical practice for the management of newly diagnosed T2DM in India. The observed benefits across glycaemic control, body weight, and cardiorenal parameters, combined with an excellent safety profile, position empagliflozin-based therapy as a cornerstone treatment option aligned with contemporary T2DM management guidelines.

DECLARATIONS

6.1 Ethics Approval and Consent to Participate

The study was conducted in accordance with the Declaration of Helsinki. Institutional ethics committee approval was obtained prior to study initiation. Patient data were anonymized and de-identified prior to analysis. The requirement for written informed consent was waived given the retrospective nature of the study.

6.2 Conflict of Interest

The authors declare no conflicts of interest.

6.3 Funding

This study was supported by Alkem Laboratories Limited. All authors have declared that no additional financial support was received from any other organization for the submitted work.

6.4 Data Availability

Data supporting the findings of this study are available from the corresponding author upon reasonable request.

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