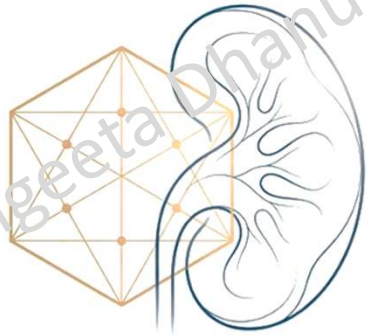
New Real-World Evidence Reveals Significant Renal Benefits of the Empagliflozin-Linagliptin FDC in Patients with Type 2 Diabetes



Preserving Renal Function in T2DM Remains a Core Clinical Challenge

High Prevalence: In specialized diabetes-care settings in India, at least one in three individuals with T2DM is estimated to have CKD.

Silent Progression: Early CKD is often asymptomatic, but kidney function can deteriorate rapidly as diabetic kidney disease progresses.

Dual Risk Factors: Sustained albuminuria (↑UACR) and declining kidney function (↓eGFR) are independent risk factors for CKD progression, cardiorenal events, and mortality.

Clinical Need: A need exists for therapies that address hyperglycemia while providing direct, potent kidney protection, even with the use of RAAS inhibitors.

Expand abbreviations
References to be added

A Dual-Mechanism Approach to Glycemic Control and Organ Protection

Empagliflozin (SGLT2-i)

- Proven to slow eGFR decline
- Reduce albuminuria
- Lower the risk of incident or worsening nephropathy (citing EMPA-REG OUTCOME)

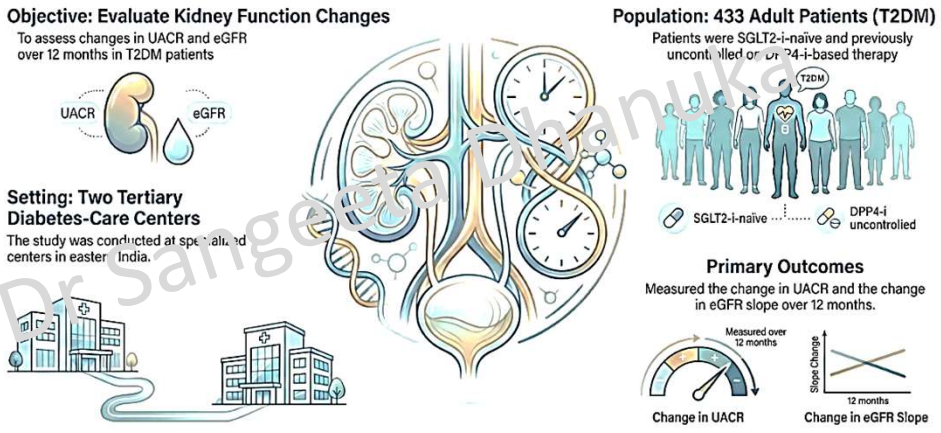
Linagliptin (DPP4-i)

- No dose adjustment needed in CKD due to biliary elimination
- Associated with slower progression and greater regression of albuminuria (citing CARMELINA)

This FDC offers complementary mechanisms for both glycemic management and cardiorenal risk reduction in a single pill, simplifying the treatment approach.

Expand abbreviations
References to be added

Study Design: A Retrospective Analysis of Clinical Practice



Expand abbreviations

A Clinically Relevant Population with Existing Comorbidities

60.3 years
Mean Age

6.6 years
Mean Duration of T2DM

63.3%
Male

54.1%
History of Hypertension

27.6%
History of Heart Failure

10.3%
Established ASCVD

This cohort reflects the complex patients commonly managed in specialist practice.

Expand abbreviations

Significant Room for Improvement in Renal and Glycemic Parameters at Baseline

Renal Status (N=433)

82.0
Mean eGFR (mL/min/1.73 m²)
(20% had eGFR < 60)

207.8
Mean UACR (mg/g)
(79% had albuminuria, UACR ≥ 30)

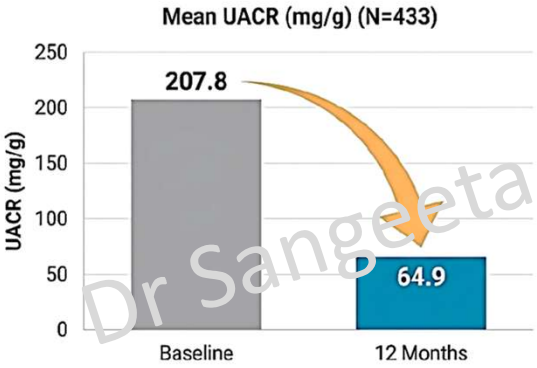
Glycemic Control (N=412)

8.3%
Mean HbA1c

The study population began with elevated albuminuria and suboptimal glycemic control, representing a high-risk group in need of effective intervention.

Expand abbreviations

A Rapid and Substantial Reduction in Albuminuria seen with Empagliflozin-Linagliptin FDC



−142.9 mg/g
Mean reduction ($p < 0.001$)

71.8%
of patients achieved a clinically significant reduction of ≥30% from baseline.

A ≥30% UACR reduction is a validated surrogate endpoint for long-term CKD protection (add citation)

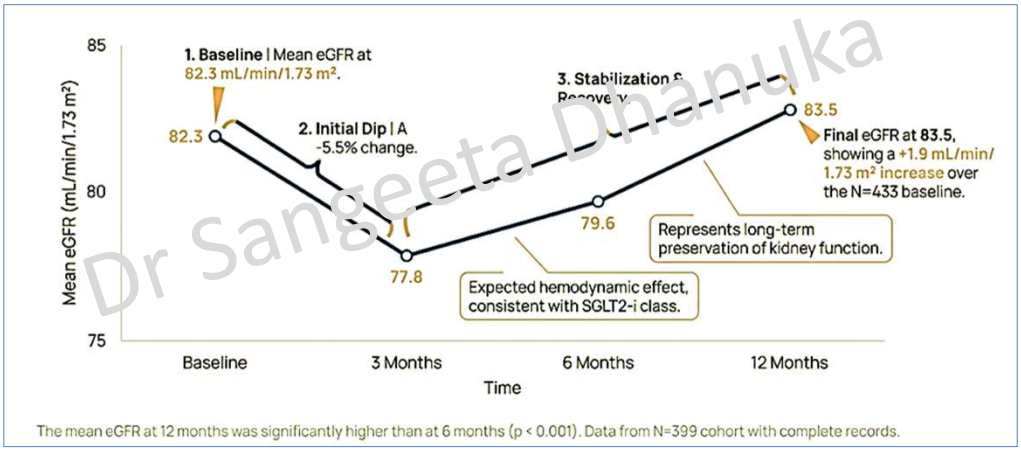
Expand abbreviations
References to be added

Patients were 2.2-times More Likely to Achieve Normo-albuminuria (A1) After 12 Months

2.2x Higher Odds of being in the A1 (normoalbuminuria) category at 12 months ($p < 0.001$).

Add footnote for albuminuria categories with reference

After an Expected Initial Dip, eGFR Stabilized and Recovered, Demonstrating Long-Term Preservation



The mean eGFR at 12 months was significantly higher than at 6 months ($p < 0.001$). Data from N=399 cohort with complete records.

Robust Improvements in Key Metabolic Parameters

Glycemic Control (HbA1c)

-1.5%

(from 8.3% to 6.7%, $p < 0.001$)

Body Weight

-3.3 kg

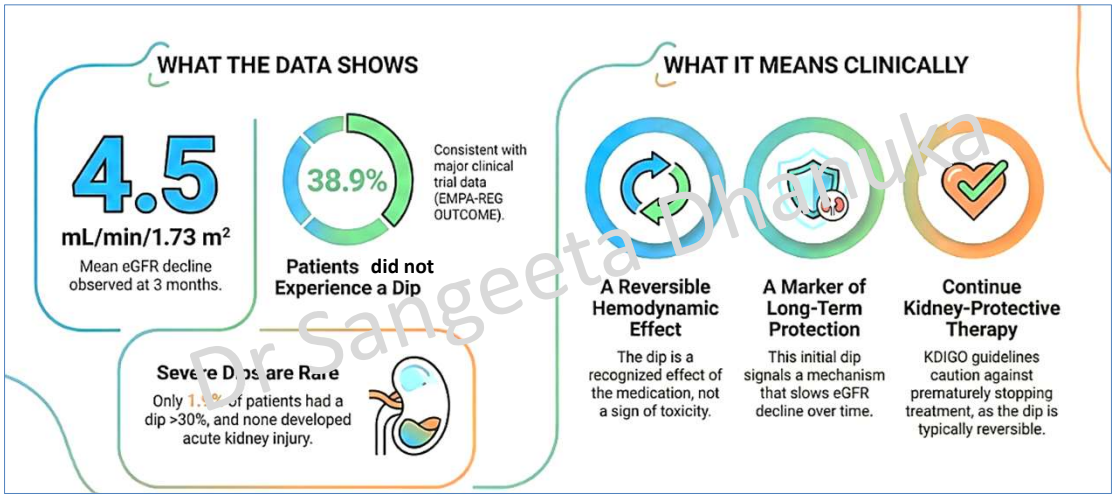
(from 69.7 kg to 66.4 kg, $p < 0.001$)

Blood Pressure

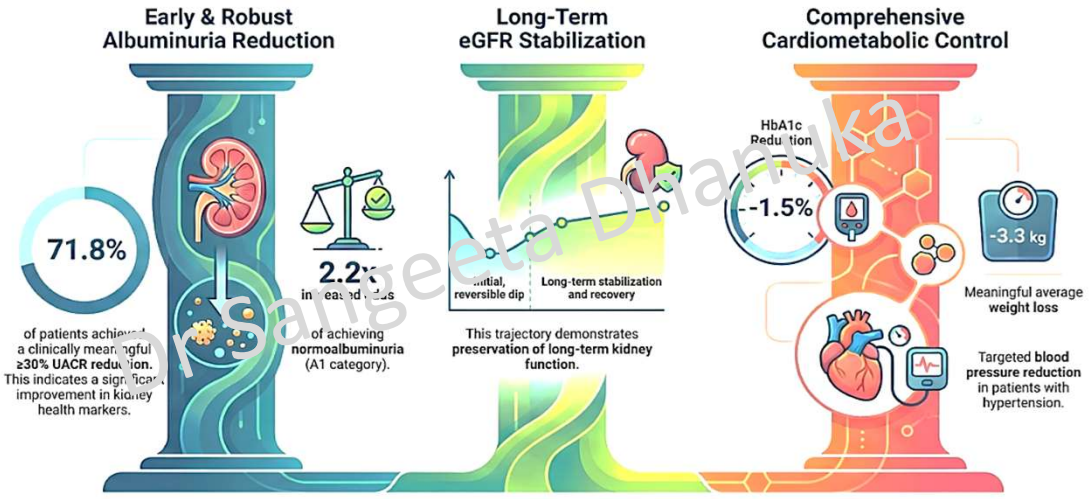
-8.9 mmHg

Significant SBP reduction in patients with baseline SBP ≥ 130 mmHg ($p < 0.05$)

Understanding the Initial eGFR Dip: A Sign of Therapeutic Action, Not Harm



Three Pillars of Clinical Benefit with Empagliflozin-Linagliptin FDC



A Key Principle for Practice: Interpret Renal Outcomes Longitudinally, Not Cross-Sectionally

What We See (A Single Snapshot)

An initial eGFR Dip at 3 months.

A reduction in UACR lab value.

What It Means (The Longitudinal Story)

A predictable hemodynamic effect that signals long-term preservation.

Early renal risk modification, a meaningful win that reduces cardiorenal risk.

Empagliflozin–Linagliptin FDC

Real-World Renal Outcomes from India

Unmet Need in T2DM & CKD

- CKD is common, progressive, and often under-recognized in T2DM.
  - Albuminuria and eGFR independently predict renal and CV outcomes.
  - Early renal intervention offers an opportunity for risk modification.

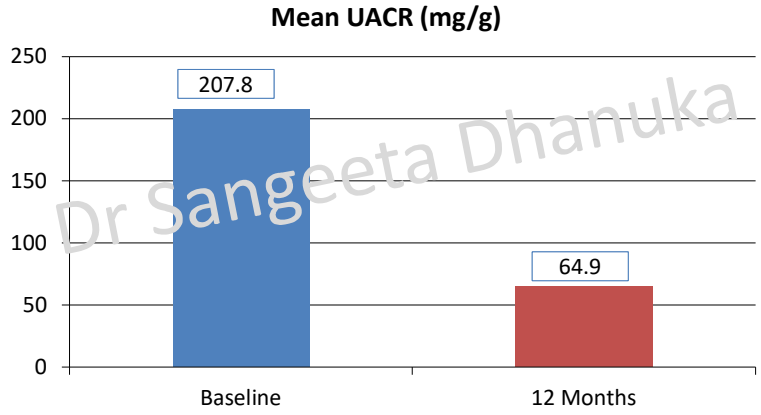
Study Overview

- Retrospective real-world observational study.
  - 433 SGLT2i-naïve T2DM patients uncontrolled on DPP-4i based combination therapy
  - initiated on Empagliflozin-Linagliptin FDC
  - 12-month follow-up in routine outpatient practice

Baseline Patient Characteristics

- Mean age 60.3 years; 63.3% male.
  - Mean HbA1c 8.3%
  - Mean GFR 82 mL/min/1.73 m^2
  - Mean UACR 207.8 mg/g
  - Hypertension: 54.1%; Heart failure: 27.6%; ASCVD: 10.3%.
  - 79% had elevated albuminuria (UACR ≥30 mg/g).

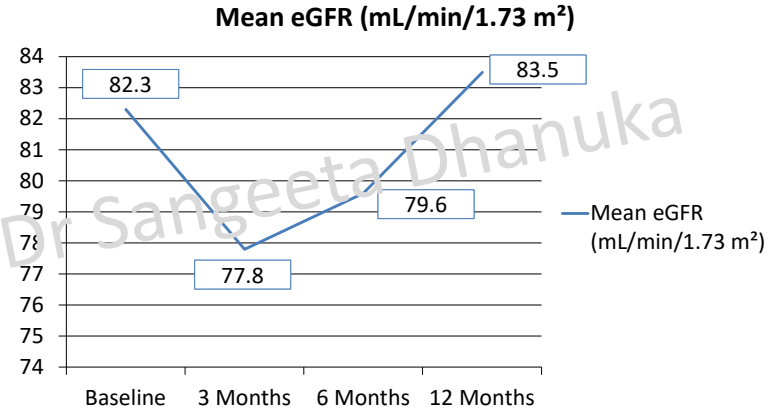
Reduction in Albuminuria (UACR)



Clinical Interpretation: UACR

- Mean UACR reduction of 142.9 mg/g over 12 months ($p < 0.001$)
  - 71.8% of patients achieved ≥30% reduction in UACR
  - Albuminuria reduction reflects early, modifiable renal risk

eGFR Dip and Recovery Over Time



Clinical Interpretation: eGFR

- Initial eGFR dip observed at 3 months (−4.5 mL/min/1.73 m²).
  - Subsequent stabilization and recovery by 12 months.
  - Pattern consistent with known hemodynamic effects of SGLT2 inhibition.

Metabolic Outcomes

- HbA1c reduction of −1.5% over 12 months.
  - Mean body weight reduction of −3.3 kg
  - Renal benefits observed alongside glycemic improvement.

Key Takeaways

- Empagliflozin–linagliptin FDC demonstrated meaningful renal benefits in real-world practice
  - Findings support albuminuria reduction and stabilization of kidney function
- Renal outcomes should be assessed longitudinally, not cross-sectionally.
  - Early eGFR dip is expected and reversible, not a safety signal.