La Renon

LINA-DKD

Linagliptin 5 mg Tablets

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Effect of linagliptin on CV outcomes and kidney outcomes in patients with type 2 diabetes at high risk of CV and kidney events

- Randomized, placebo-controlled, multicenter noninferiority trial.
- **Total Patients :** N=6979

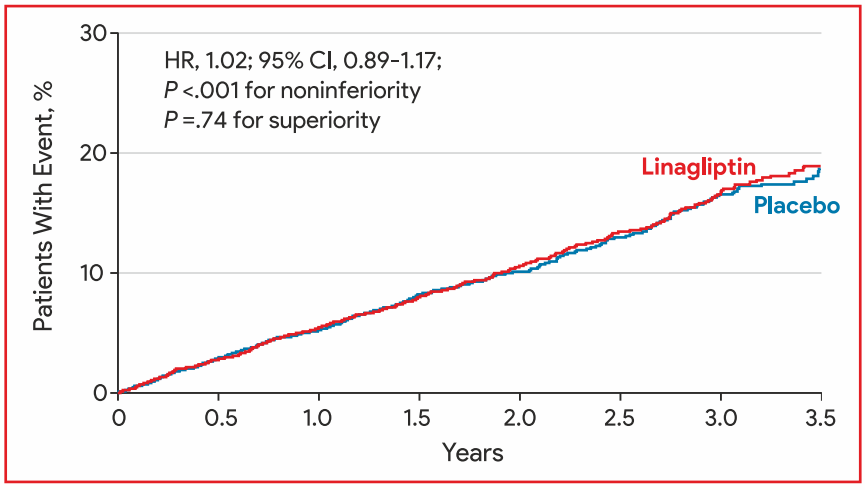
	Linagliptin Group	Placebo Group
Number of Patients (N)	3494	3485
Dose	Linagliptin 5 mg/day + Standard of Care	Matching Placebo + Standard of Care

End Points :

Primary Endpoints	Secondary Endpoints
Time to first occurrence of the composite of CV death, nonfatal myocardial infarction, or nonfatal stroke.	Time to first occurrence of adjudicated death due to renal failure, ESRD, or sustained 40% or higher decrease in eGFR from baseline.

Results :

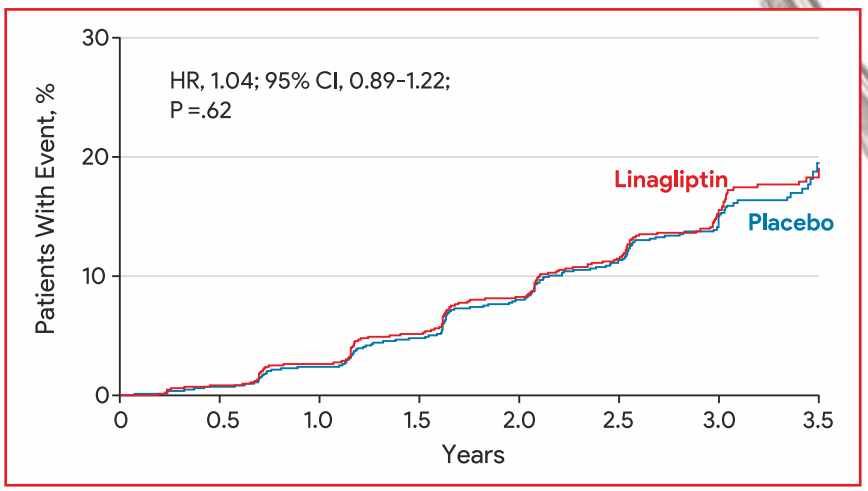
Time to primary 3-point MACE outcome -



Long-term CV safety profile

The primary composite 3-point MACE outcome occurred in 434 (12.4%) of 3494 patients randomized to linagliptin (5.77 per 100 person-years) and 420 (12.1%) of 3485 patients randomized to placebo (5.63 per 100 person-years).

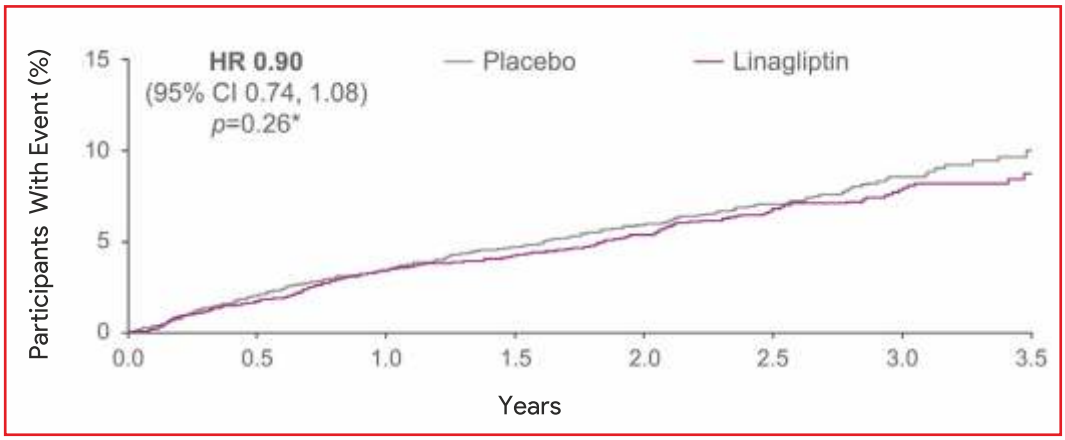
Time to secondary kidney outcome



Long-term kidney safety profile

The kidney outcome occurred in 327 of 3494 (9.4%) and 306 of 3485 (8.8%) patients in Linagliptin and Placebo group respectively.

No increased risk of hospitalization for heart failure



*Two sided *P* value HR- Hazard Ratio

Rates of hospitalization for heart failure did not differ between treatment groups: 209/3494 (6.0%) and 226/3485 (6.5%) in the linagliptin and placebo groups, respectively.

Conclusion :

- Linagliptin demonstrated a long-term CV safety profile in patients with T2D, including those with CV and/or kidney disease.
- Linagliptin demonstrated a reassuring long-term kidney safety profile.
- Linagliptin showed no increase in risk of hospitalization for heart failure, even in patients at high risk of heart failure.

References:
1. JAMA. 2019;321(1):69-79
2. Circulation. 2019;139:351–361

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Linagliptin 5 mg Tablets

Background :

Many oral anti-diabetic drugs are eliminated by the kidney to some extent. If the dosage is not appropriately decreased in a patient with chronic kidney disease, drug concentrations can increase, risking adverse drug reactions. On the other hand, unnecessary decreases in dosage may result in undertreatment, or changing to an alternate drug with a narrower therapeutic index, lowers efficacy or both.

Linagliptin is the only one that does not need dose adjustment according to eGFR because it is metabolized in the liver and mainly excreted in bile, unlike the others that are cleared by the kidneys.

Description :

LINA-DKD contains Linagliptin 5 mg Tablets. Linagliptin is an oral, highly selective inhibitor of dipeptidyl peptidase-4 and is the first agent of its class to be eliminated predominantly via a nonrenal route.

Indication :

LINA-DKD is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Mechanism of action :

Linagliptin is an inhibitor of DPP-4, an enzyme that degrades the incretin hormones glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). Thus, linagliptin increases the concentrations of active incretin hormones, stimulating the release of insulin in a glucose-dependent manner and decreasing the levels of glucagon in the circulation. Both incretin hormones are involved in the physiological regulation of glucose homeostasis.

Dosage and Administration :

The recommended dose of **LINA-DKD** is 5 mg once daily or as prescribed by the doctor.

Key Features :

- √ ~85% of orally administered linagliptin is excreted via the bile and gut & ~5% of linagliptin is excreted via the kidneys.
- √ No dose adjustment is required for patients with renal impairment.
- √ Reduces albuminuria burden and HbA1c, without affecting CV or kidney risk.
- √ Improves Renal Function
- √ Shows long-term CV & kidney safety profile

References

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2. Aust Prescr 2019; 42:163–7
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6. J Diabetes Investig 2017; 8: 19–28

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