La Renon

Dapaconic

Dapagliflozin 5 mg & 10 mg Tablets

Catalyst for

DAPA-CKD TRIAL

Dapagliflozin in Patients with Chronic Kidney Disease

Randomized, Double-blind,
Placebo-controlled, multicenter trial

Dapagliflozin 10 mg daily N=2152	Placebo N=2152	DURATION: 2.4 YEARS

INCLUSION CRITERIA:

Adults with or without type 2 diabetes who had an estimated GFR of 25 to 75 ml/min and a urinary albumin-to-creatinine ratio of 200 to 5000 mg/g.

OUTCOMES:

The primary outcome was a composite of a sustained decline in the estimated GFR of at least 50%, end-stage kidney disease, or death from renal or cardiovascular causes.

GFR: Glomerular Filtration Rate

RESULTS:

	Dapagliflozin	Placebo
Primary composite outcome	9.2 %	14.5 %
Composite Kidney outcomes	6.6 %	11.3 %
Composite Cardiovascular outcomes	4.6 %	6.4 %
Death from any cause	4.7 %	6.8 %

CONCLUSION:

Among patients with chronic kidney disease, regardless of the presence or absence of diabetes, the risk of a composite of a sustained decline in the estimated GFR of at least 50%, end-stage kidney disease, or death from renal or cardiovascular causes was significantly lower with dapagliflozin than with placebo.

Reference: N Engl J Med 2020; 383:1436-1446

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Mechanism of Action of DAPACONIC

Dapagliflozin is in a class of medications called Sodium-Glucose Cotransporter-2 (SGLT2) inhibitors.

Dapagliflozin inhibits the Sodium-Glucose Cotransporter-2 (SGLT2) which is primarily located in the proximal tubule of the nephron.

SGLT2 facilitates 90% of glucose resorption in the kidneys and so its inhibition allows for glucose to be excreted in the urine. This excretion allows for better glycemic control and potentially weight loss in patients with type 2 diabetes mellitus.

INDICATION	DOSING
To **slow the progression of Chronic Kidney Disease** in patients with or without diabetes	10 mg once daily
As an adjunct to diet and exercise **to improve glycemic control in adults with type 2 diabetes mellitus**	5 mg once daily, taken in the morning. The dose can be increased to 10 mg once daily
In patients with heart failure with reduced ejection fraction, **to reduce the risk of CV death and hospitalization for heart failure**	10 mg once daily
In patients with T2D with multiple CV risk factors, **to reduce the risk of hospitalization for heart failure**	

USP

- Prevents & reduces progression of kidney disease
- Convenient Once Daily Dosing
- Reduces hospitalization for heart failure
- Reduces cardiovascular death & all-cause mortality

Warning: Cases of a rare but serious infection of the genitals and area around the genitals have been reported with this class of type 2 diabetes medicines i.e., Sodium-Glucose Co-transporter-2 (SGLT2) inhibitors. This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene.

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Reference:
1. Circulation. 2019;139:2528–2536
2. Lancet Diabetes Endocrinol. 2019 Aug;7 (8):606-617.
3. N Engl J Med 2020; 383:1436-1446

THE DERIVE STUDY

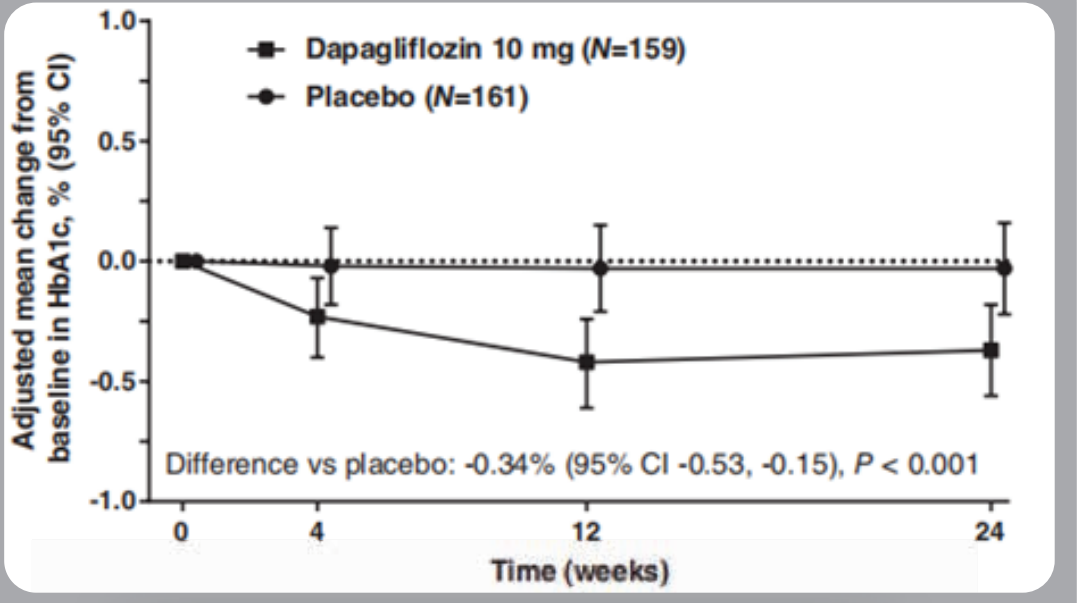
Efficacy and Safety of Dapagliflozin in patients with T2D and moderate renal impairment

A randomized, double-blind, 2-arm, parallel group, placebo-controlled study.

Patients with T2D and CKD stage 3A (eGFR, 45-59 mL/min/1.73 m^2).

DURATION: 24 WEEKS

Placebo (n = 161)	Dapagliflozin 10 mg daily (n = 160)



At week 24, compared with placebo, dapagliflozin significantly decreased HbA1c (−0.34%); body weight (−1.25 kg), and fasting plasma glucose (−0.9 mmol/L).

Decreases from baseline in eGFR were greater with dapagliflozin than placebo at Week 24 (−2.49 mL/min/1.73m^2), however, eGFR returned to baseline levels at Week 27 (3 weeks post-treatment).

CONCLUSION

Significant improvements in HbA1c and fasting plasma glucose over 24 weeks in patients with T2D and stage 3A CKD were demonstrated with use of dapagliflozin. The findings of this study support a positive benefit/risk profile of dapagliflozin in patients with T2D and CKD stage 3A.

*T2D -Type 2 Diabetes

Reference: Diabetes Obes Metab. 2018;20:2532–2540