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Study Design

Phase	Phase III	Design	Multicenter, randomized, double-blind, placebo-controlled trial
Sample Size	n=4,744	Evidence Grade	A

Intervention vs Comparator

Intervention	Comparator
Dapagliflozin (10 mg once daily)	Placebo

Primary Endpoint

Composite of worsening heart failure (hospitalization or urgent visit for heart failure) or cardiovascular death

Key Results

Dapagliflozin significantly reduced the primary composite endpoint compared to placebo. The event rate for the primary endpoint was 16.3% in the placebo group and 11.6% in the dapagliflozin group, corresponding to a Hazard Ratio of 0.74.

p = <0.001 95% CI: 95% CI 0.65-0.85 NNT: 21 (to prevent one primary composite endpoint event over a median follow-up of 18.2 months)

Limitations

- Predominantly white study population, potentially limiting generalizability to other ethnic groups.
- Median follow-up duration of 18.2 months may not fully capture very long-term effects or safety profiles.
- Patients with type 1 diabetes were excluded, and those with very low eGFR (<30 mL/min/1.73 m²) were also excluded, limiting applicability in these specific populations.

Clinical Implications

- Dapagliflozin significantly reduces the risk of worsening heart failure and cardiovascular death in patients with heart failure with reduced ejection fraction (HFrEF), irrespective of the presence of type 2 diabetes.
- It represents a new foundational therapy for HFrEF, offering substantial clinical benefits beyond traditional guideline-directed medical therapy.
- The findings support the use of dapagliflozin to improve patient outcomes, reduce hospitalizations, and decrease mortality in a broad population of HFrEF patients.