Mass General Brigham

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Scientific Sessions

RACIAL AND ETHNIC DIFFERENCES IN SIMULTANEOUS INITIATION OF FINERENONE AND EMPAGLIFLOZIN ON URINARY ALBUMIN-TO-CREATININE RATIO: THE CONFIDENCE TRIAL

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American Heart Association.

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DISCLOSURE SLIDE

The CONFIDENCE Trial was sponsored by Bayer.

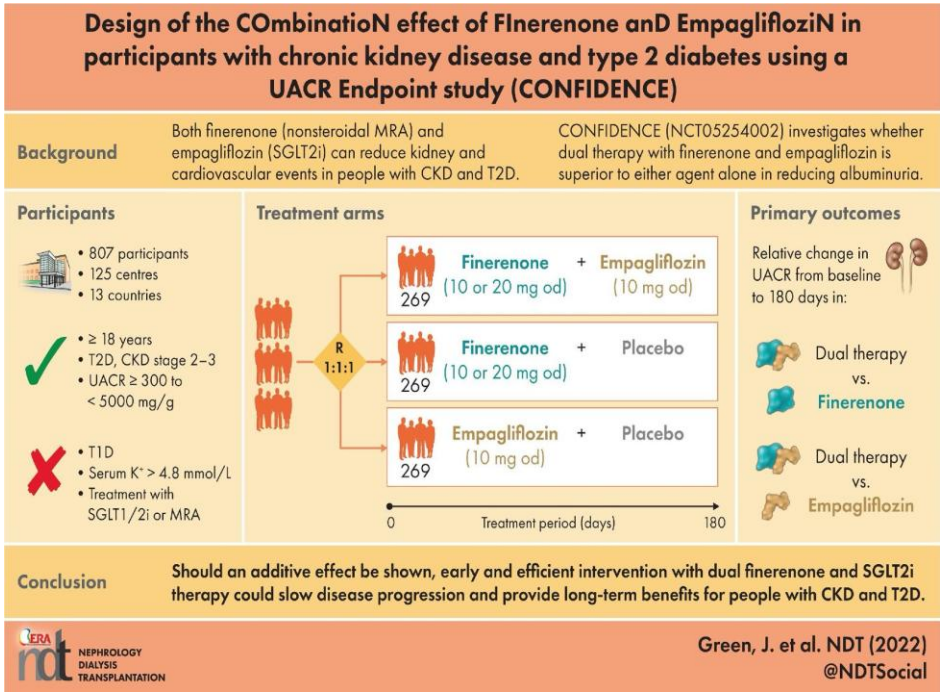
Dr Vaduganathan has received research grant support, served on Advisory Boards, or had speaker engagements with American Regent, Amgen, AstraZeneca, Bayer AG, Baxter Healthcare, Bristol Myers Squibb, Boehringer Ingelheim, Chiesi, Cytokinetics, Fresenius Medical Care, Idorsia Pharmaceuticals, Lexicon Pharmaceuticals, Merck, Milestone Pharmaceuticals, Novartis, Novo Nordisk, Pharmacosmos, Relypsa, Roche Diagnostics, Sanofi, and Tricog Health; and has participated on Clinical Trial Committees for studies sponsored by AstraZeneca, Galmed, Novartis, Bayer AG, Occlutech, and Impulse Dynamics.

INTRODUCTION

Background

- Chronic kidney disease (CKD) affects individuals of all races and ethnicities, but disease progression, access to guideline-directed therapy, and clinical trial representation vary substantially across racial/ethnicity groups.
- Finerenone and SGLT2 inhibitors such as empagliflozin each reduce albuminuria and slow CKD progression through complementary mechanisms; combining the two may provide additive benefit, but this has not been well characterized across diverse populations.
- In this post hoc analysis, we examined the relative change in log-transformed UACR from baseline to day 180 by treatment arm within each self-reported racial and ethnic subgroup.

Study Design and Randomized Treatments



References: *Nephrol Dial Transplant*, Volume 38, Issue 4, April 2023, Pages 894–903, https://doi.org/10.1093/ndt/gfac198

METHODS

Study Population

- 800 randomized participants with CKD and type 2 diabetes; 789 (99%) had self-reported race-ethnicity data
- n=371 Asian, n=273 non-Hispanic White, n=78 Hispanic White, and n=67 non-Hispanic Black

Treatment Arms

- 1:1:1 randomization to empagliflozin (n=267), finerenone (n=264), or finerenone plus empagliflozin combination (n=269).
- UACR assessed on-treatment at Day 180 and off-treatment at Day 210.

Study Outcomes

- Primary: UACR change from baseline, expressed as adjusted geometric mean ratio (GMR).
- Secondary: odds of achieving ≥30%, ≥40%, and ≥50% UACR reduction.
- Safety: adverse events, hyperkalemia, and ≥30% eGFR decline.

Statistical Analysis

- Linear regression models of log-transformed UACR (for GMRs) and logistic regression models (for reduction thresholds) were adjusted for baseline log-UACR (continuous) and randomization stratification factors (eGFR and UACR category).
- Race-ethnicity subgroup analyses used treatment-by-subgroup interaction terms; joint Wald tests assessed heterogeneity.

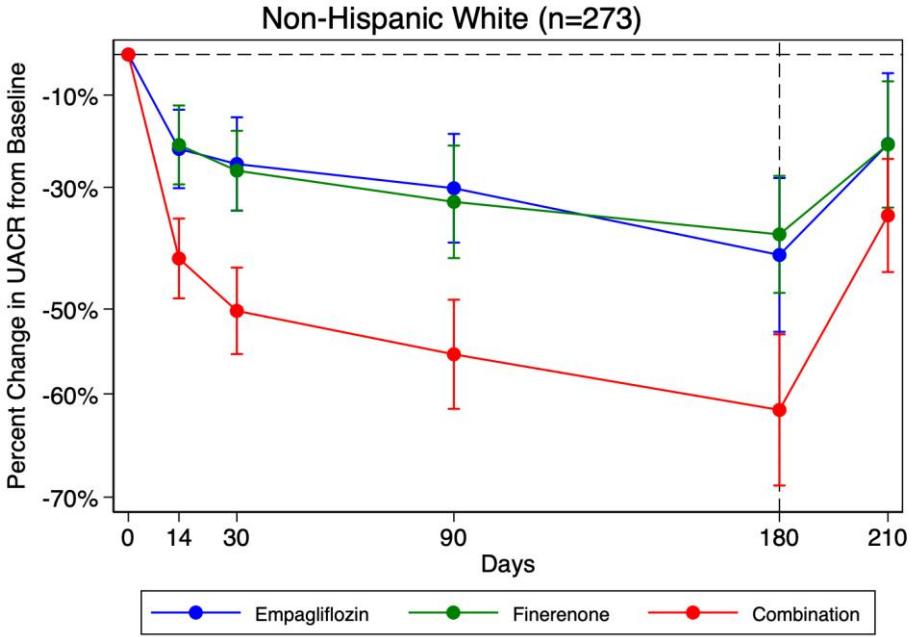
RESULTS

Select Baseline Characteristics

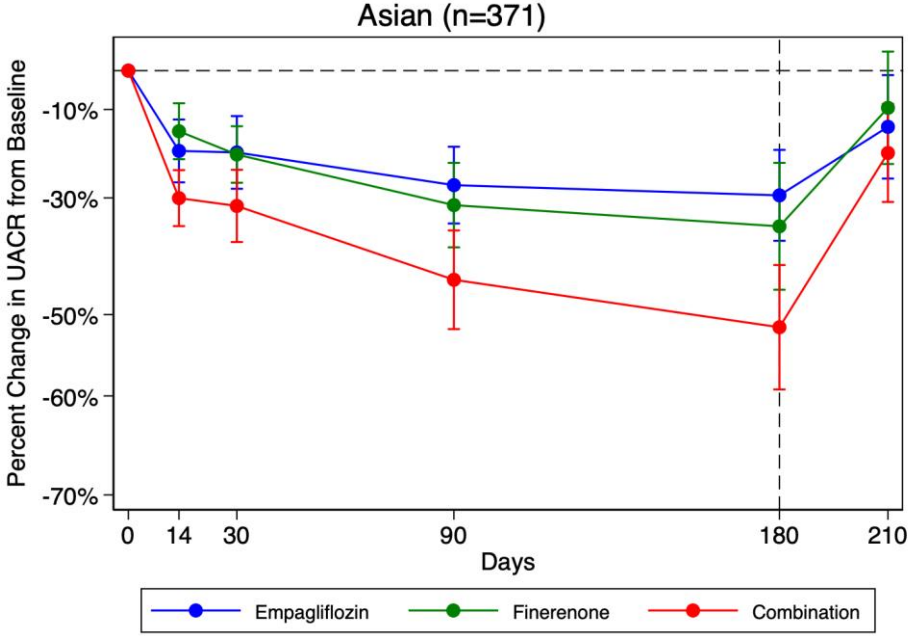
Characteristics	Hispanic White (n=78)	Non-Hispanic White (n=273)	Non-Hispanic Black (n=67)	Asian (n=371)
Age, years, mean ± SD	68.1 ± 8	70.5 ± 9	**61.9 ± 12** ↓	**64.0 ± 11** ↓
Male sex, n (%)	47 (60)	214 (78)	**39 (58)** ↓	294 (79)
Baseline BMI, kg/m², mean ± SD	31.7 ± 7	32.1 ± 6	31.8 ± 6	**26.2 ± 4** ↓
ASCVD history present, n (%)	26 (33)	100 (37)	16 (24)	**79 (21)** ↓
Diuretic use, n (%)	33 (42)	136 (50)	37 (55)	**78 (21)** ↓
Insulin use, n (%)	32 (41)	136 (50)	41 (61)	**101 (27)** ↓

RESULTS

Change in urinary-albumin-creatine ratio overtime from baseline to 180 days and 30 days after treatment, within each racial-ethnic subgroup



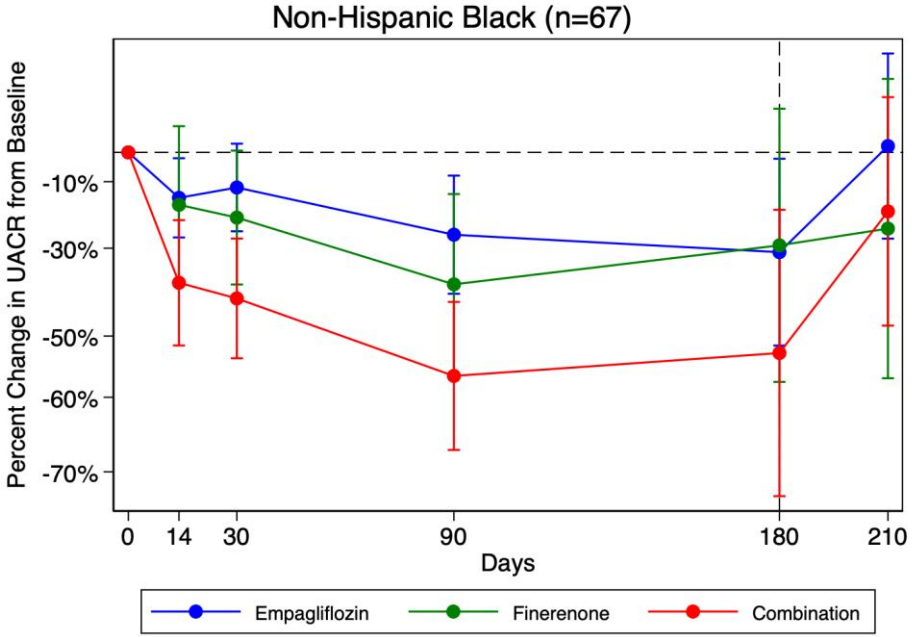
Treatment Effect at Day 180
Combination vs. Finerenone: 0.63 (0.48–0.83)
Combination vs. Empagliflozin: 0.65 (0.49–0.85)



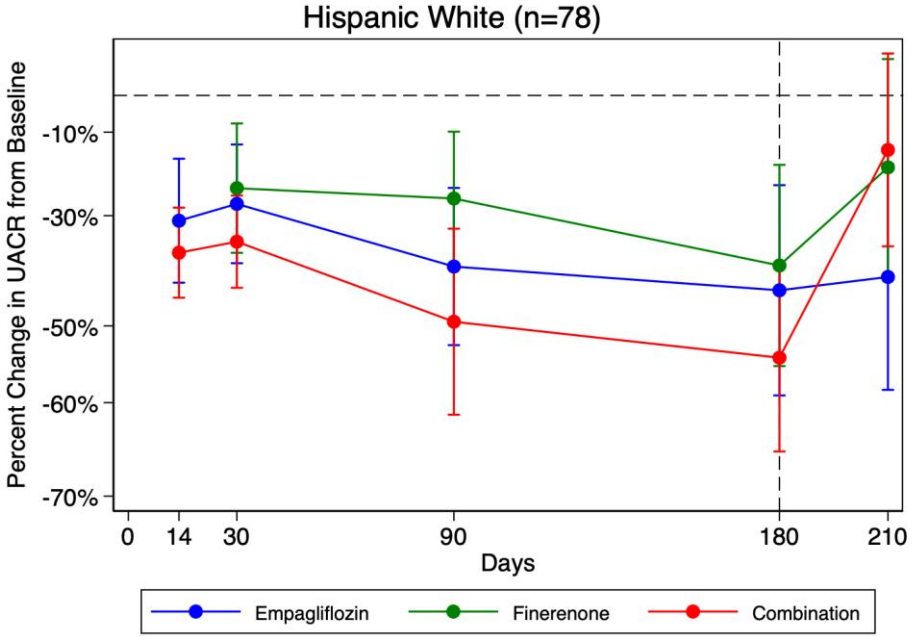
Treatment Effect at Day 180
Combination vs. Finerenone: 0.73 (0.58–0.91)
Combination vs. Empagliflozin: 0.67 (0.53–0.85)

RESULTS

Change in urinary-albumin-creatine ratio overtime from baseline to 180 days and 30 days after treatment, within each racial-ethnic subgroup



Treatment Effect at Day 180
Combination vs. Finerenone: 0.65 (0.32–1.32)
Combination vs. Empagliflozin: 0.68 (0.35–1.31)



Treatment Effect at Day 180
Combination vs. Finerenone: 0.75 (0.47–1.20)
Combination vs. Empagliflozin: 0.85 (0.55–1.31)

CONCLUSION

- Combination therapy with finerenone and empagliflozin demonstrated consistent superiority over monotherapy alone in reducing albuminuria across racial and ethnic subgroups, with no statistically significant heterogeneity of treatment effect, supporting its efficacy regardless of race or ethnicity in patients with CKD and T2DM.

- These findings support generally consistent efficacy and safety of finerenone-empagliflozin combination therapy across race-ethnicity subgroups.

- Prospective studies with adequate representation of diverse populations are needed to confirm these findings across race-ethnicity subgroups.

- Improving the prescription of effective and safe medications for diverse patients with CKD remains a critical dimension to address to improve health equity and kidney outcomes

THANK YOU

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