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Patients With Focal Segmental Glomerulosclerosis (FSGS) Achieved Low Proteinuria Targets Earlier and More Often With Sparsentan (SPAR) vs Irbesartan (IRB) in DUPLEX

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INTRODUCTION

- There are no approved pharmacologic therapies for FSGS,[1] a condition associated with substantial risk of kidney failure,[2] underscoring the unmet treatment need
- SPAR is a non-immunosuppressive DEARA[3,4] that led to rapid and sustained proteinuria reductions in patients with FSGS in the phase 3 DUPLEX trial[5]

AIM

- We assessed the effects of SPAR vs IRB on low proteinuria targets, including CR of proteinuria and the FSGS partial remission endpoint, and the impact of CR of proteinuria and FSGS partial remission on kidney failure in DUPLEX

METHOD

Analysis of patients who achieved proteinuria thresholds with SPAR vs IRB

Analysis of kidney failure in patients achieving CR of proteinuria or the FSGS partial remission endpoint regardless of treatment*

SPAR (n=184) vs maximum labeled dose IRB (n=187) (double blind)†

SPAR: 800 mg/d†
IRB: 300 mg/d†

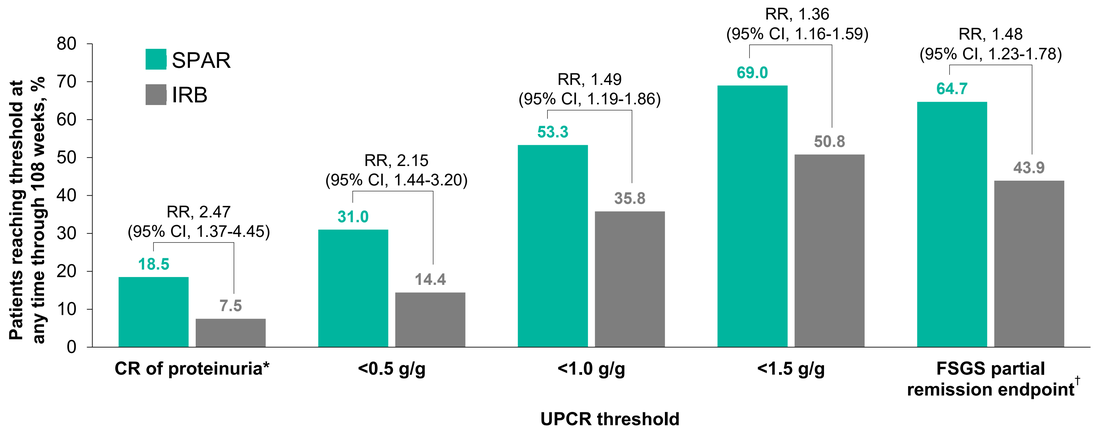
N=371 adult and pediatric patients with FSGS (without secondary causes)

Inclusion criteria:
UPCR ≥1.5 g/g
eGFR ≥30 mL/min/1.73 m^2

*CR of proteinuria was defined as UPCR of <0.3 g/g. The FSGS partial remission endpoint was defined as UPCR of ≤1.5 g/g and >40% reduction from baseline.
† Approximately 90% of patients reached the target dose (800 mg/d of SPAR or 300 mg/d of IRB, titrated after 2 weeks of 400-mg/d SPAR or 150-mg/d IRB) in both treatment arms.

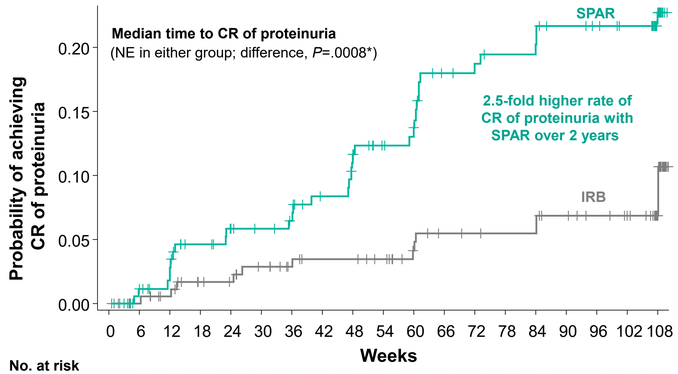
RESULTS

Patients Achieved Low Proteinuria Thresholds More Often With SPAR vs IRB



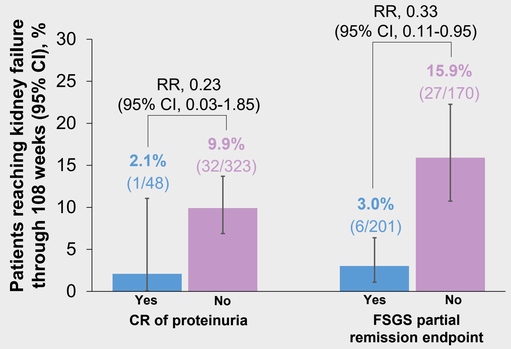
*CR of proteinuria was defined as UPCR of <0.3 g/g. †The FSGS partial remission endpoint was defined as UPCR of ≤1.5 g/g and >40% reduction from baseline.

Patients Achieved CR of Proteinuria Earlier With SPAR vs IRB



*P value generated from a stratified Cox proportional hazards model with treatment and baseline log (UPCR) as covariates, stratified by randomization stratification factors.

Irrespective of Treatment, Fewer Patients Who Reached CR of Proteinuria or FSGS Partial Remission Progressed to Kidney Failure*



*CR of proteinuria was defined as UPCR of <0.3 g/g. FSGS partial remission was defined as UPCR of ≤1.5 g/g and >40% reduction from baseline. Kidney failure was defined as confirmed eGFR of <15 mL/min/1.73 m^2 or initiation of kidney replacement therapy.

CONCLUSIONS

- Clinically meaningful low proteinuria thresholds, including CR of proteinuria or the FSGS partial remission endpoint, were achieved earlier and more often with SPAR vs IRB
- Consistent with results from PARASOL,[6] patients who reached CR of proteinuria or the FSGS partial remission endpoint, irrespective of treatment, had a lower risk of progressing to kidney failure
- Taken together, findings support SPAR's nephroprotective benefit in FSGS

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ABBREVIATIONS

CR, complete remission; DEARA, dual endothelin angiotensin receptor antagonist; eGFR, estimated glomerular filtration rate; FSGS, focal segmental glomerulosclerosis; IRB, irbesartan; NE, not estimable; RR, relative risk; SPAR, sparsentan; UPCR, urine protein-to-creatinine ratio.

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