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Enclosure:

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Treatment Patterns, Response, and Relapse in Minimal Change Disease: A US Registry Study

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Study Funding

- This study was funded by Otsuka.
- The study was carried out in CureGN.
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  - Patient recruitment is supported by NephCure.

Background and Objective

- Minimal change disease (MCD) is a histologic lesion associated with immune-mediated nephrotic syndrome (NS).
  - MCD accounts for approximately 15% of patients with immune-mediated NS among adults (Vivarelli et al., 2017).

- Corticosteroids are the first-line treatment for MCD (Rovin et al., 2021).
  - Initial response to corticosteroid treatment is common.
  - However, relapse and subsequent use of additional immunosuppression remain frequent (Vivarelli et al., 2017), indicating challenges in achieving durable disease control.

- Long-term kidney function is generally preserved in steroid-responsive MCD.
  - However, adults may experience frequent relapses and substantial cumulative treatment exposure; complications include acute kidney injury and thromboembolic events (Maas et al., 2017; Go et al., 2021).

- There is limited real-world evidence about treatment patterns and outcomes in this population.

OBJECTIVE:

This study describes demographics, clinical characteristics, treatment patterns, and outcomes among US adults with biopsy-confirmed MCD and NS.

Study Approach

Study Design

- Descriptive cohort study of adults in the US with a biopsy showing evidence of MCD.
- The date of the biopsy was the index date.
- Followed participants from biopsy to registry disenrollment, end of available data, or death.

Data Source

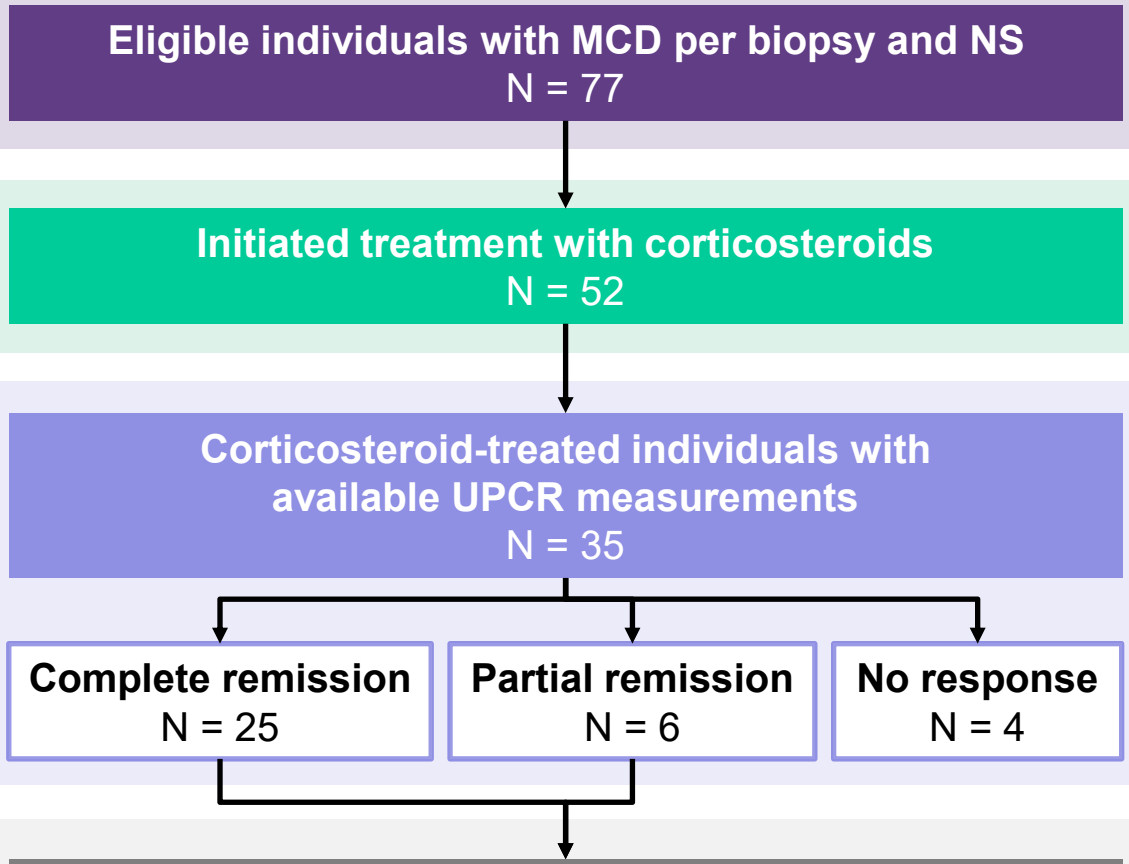
- CureGN Glomerular Disease Registry (December 2014-September 2025)
  - Multi-center prospective observational study of participants with biopsy-confirmed glomerular disease.
  - Only US sites were used for this study.

Eligibility

- Inclusion criteria
  - Aged ≥18 years at biopsy
  - Be enrolled in CureGN within 1 year of biopsy
  - Have evidence of NS (a recorded diagnosis or UPCR > 3.5 g/g)
- Exclusion criteria
  - Kidney transplant
  - > 3 months of corticosteroid use before biopsy

CureGN = CureGN Glomerular Disease Registry; MCD = minimal change disease; NS = nephrotic syndrome; UPCR = urine protein to creatinine ratio; US = United States.

Study Population and Analyses



- Describe characteristics at biopsy
- Describe initial immunosuppressive treatment option and treatment changes
- Describe time to treatment initiation within 1 year of biopsy
- Describe treatment response based on UPCR measurements within 8 months of treatment initiation
  - Complete remission: UPCR < 0.3 g/g
  - Partial remission: UPCR < 50% of baseline and 0.3-3.5 g/g
- Describe relapse within 2 years of response
  - Those with complete remission: UPCR > 0.3 g/g
  - Those with partial remission: UPCR > 3.5 g/g or > 50% increase from baseline
- Evaluate predictors of relapse using Cox models

MCD = minimal change disease; NS = nephrotic syndrome; UPCR = urine protein to creatinine ratio.

Results: Characteristics at Biopsy and Initial Treatment

Baseline Characteristics at Biopsy

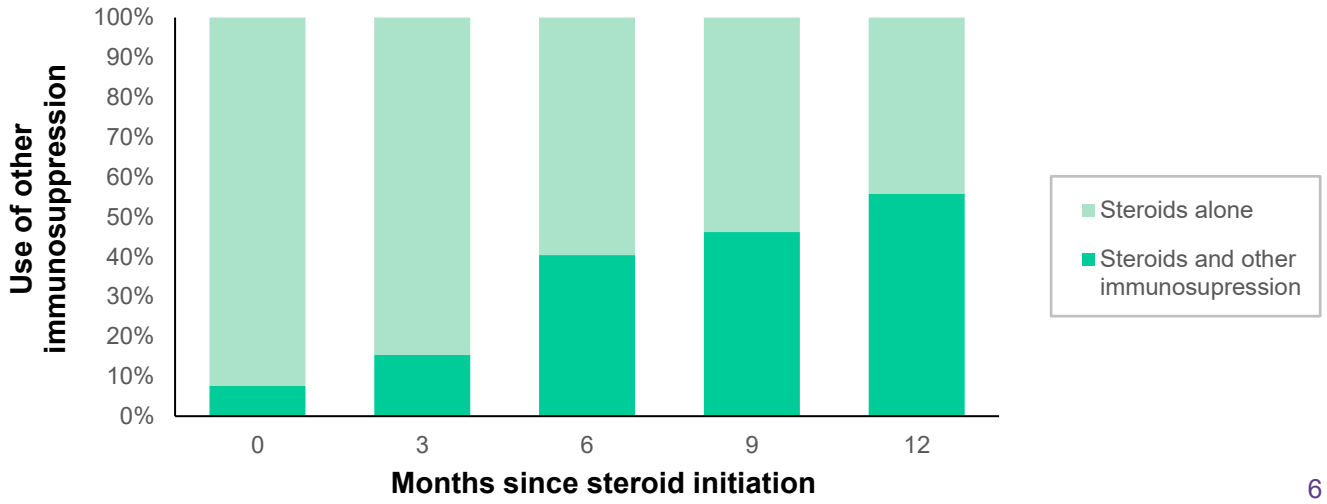
Characteristic	Value (N = 77)
Age in years, mean (SD)	45 (18)
Sex, %	
Female	66%
Male	34%
Obesity, %	42%
eGFR , median (Q1, Q3)	82 (66, 106)
UPCR, median (Q1, Q3)	6.5 (3.7, 9.0)

eGFR = estimated glomerular filtration rate, expressed as mL/min/1.73 m²; Q1, Q3 = first and third quartiles; SD = standard deviation; UPCR = urine protein to creatinine ratio, expressed as g/g.

Treatment Initiation

- 52 participants (68%) initiated corticosteroids within 1 year of biopsy
  - 92% with steroids alone
  - 8% with steroids and another immunosuppressant
- Mean time to initiation = 28 days (SD, 60)
  - 89% initiated within 6 weeks
- 56% had received additional immunosuppression by 12 months

Use of Non-Corticosteroid Immunosuppressants After Steroid Initiation



Results: Treatment Response and Relapse

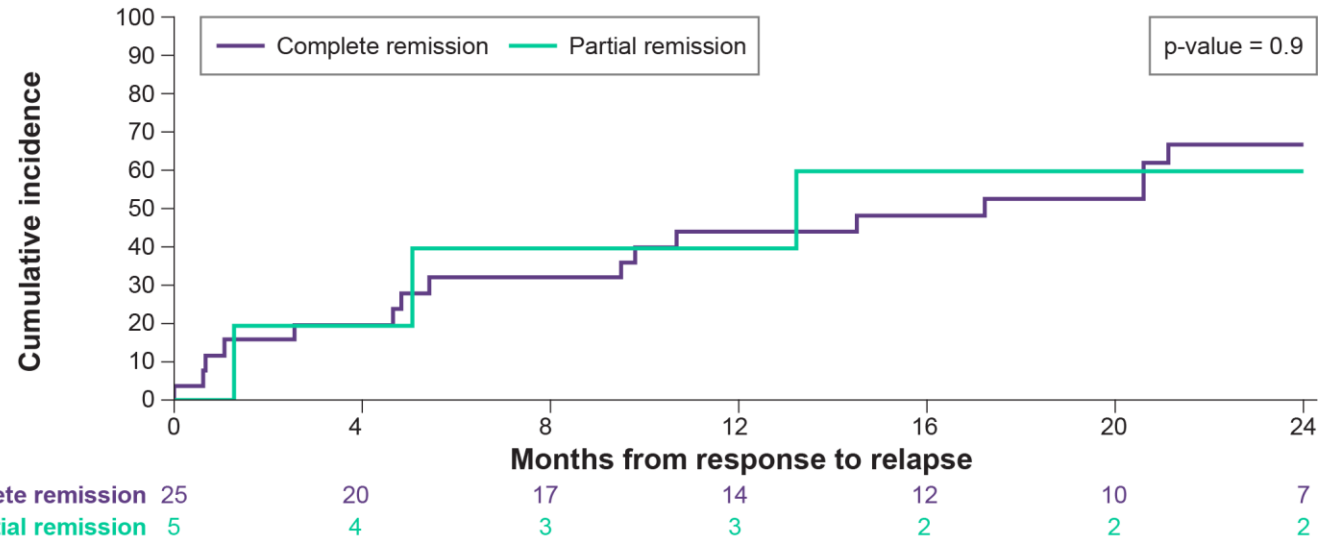
Treatment Response

- Among corticosteroid initiators, 35 participants had available UPCR data for response assessment.
- 88.6% achieved an initial response:
  - 71.4% complete remission
  - 17.1% partial remission
- Median (Q1, Q3) time-to-response (either complete or partial) among those who responded:
  - 53 days (28, 135)

Relapse

- Despite the high initial response rate, relapse was frequent among responders (complete or partial):
  - 43% relapsed within 1 year
  - 63% relapsed within 2 years
- Median (Q1, Q3) time-to-relapse (among those who relapsed):
  - 166 days (40, 441)
- No statistically significant predictors of relapse were identified.
  - Estimates were imprecise given the small analysis population.

Time-to-Relapse after treatment response by remission status



Q1, Q3 = first and third quartiles; UPCR = urine protein to creatinine ratio.

Discussion

Strengths

- **Diverse study population** from throughout the US.
- **Rich clinical data** about individuals with biopsy-confirmed glomerular disease.
- **Standardized visit** and **data collection protocols.**
- **Real-world treatment decisions reflect routine clinical practice**, enabling the ability to study different treatment approaches.

Limitations

- Reliant on data as recorded in the registry; some data may be missing or unavailable.
  - Response and relapse ascertainment depended on the availability and timing of clinically collected UPCR measurements
- Small sample sizes and limited follow-up for some analyses.

UPCR = urine protein to creatinine ratio; US = United States.

Conclusions



Most adults with MCD initiated corticosteroids soon after biopsy.



Achieving an initial proteinuria response—including complete remission—was common.

- However, more than half of participants received additional immunosuppression within 12 months.
- Nearly two-thirds of evaluable responders relapsed within 2 years.



These findings highlight the challenge of maintaining durable disease control in MCD and the need for treatment approaches that achieve sustained remission.

MCD = minimal change disease.

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Thank You
Contact us:

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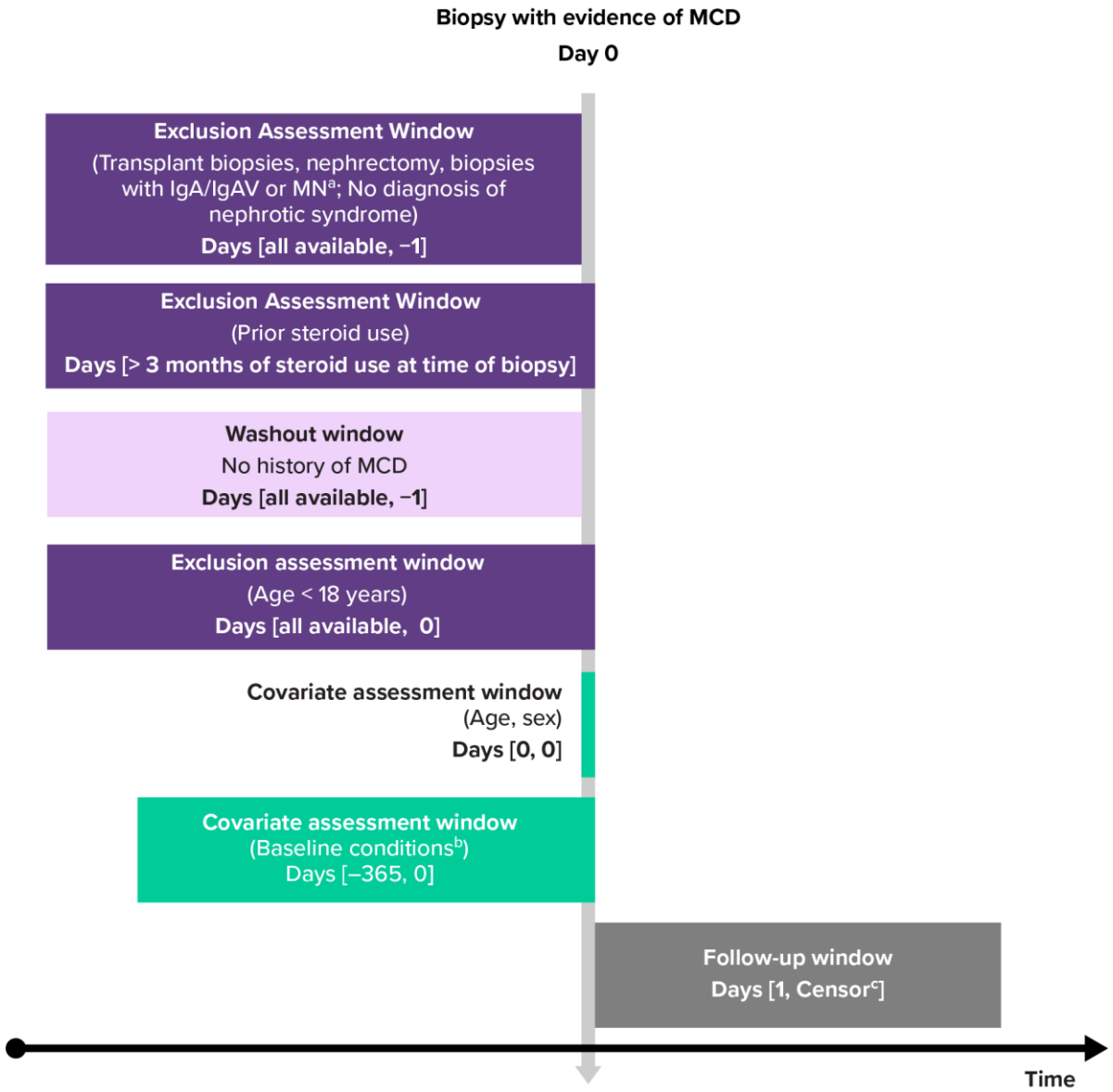
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Variable Assessment Windows



- Variables were identified from recorded registry data
  - Demographic characteristics
  - Disease severity
  - Clinical characteristics and comorbidities
  - Treatment
  - Outcomes

[a] A given participant could have had multiple biopsies with diagnoses for multiple conditions. Nephrotic syndrome was defined as UPCR > 3.5g/g.
[b] Baseline conditions included sociodemographic factors, clinical risk factors, laboratory measures, and medications. The assessment timeframe varied by covariate depending on when the information was collected in CureGN. Information after the Cohort Entry date was considered for some covariates.
[c] Earliest of outcome of interest (objective specific), mortality, disenrollment from the registry, or end of the data/study period.

Characteristics of Responders and Nonresponders

Characteristic	Responders (complete or partial) (N = 31)	Nonresponders (N = 4)
Age in years, mean (SD)	45 (18)	41 (18)
Sex, %		
Female	68%	100%
Male	32%	0%
Obesity, %	21%	0%
Baseline eGFR, median (Q1, Q3)	91 (69, 107)	89 (66, 113)
Baseline UPCR, median (Q1, Q3)	7.6 (5.7, 10.1)	6.1 (4.5, 9.3)

eGFR = estimated glomerular filtration rate, expressed as mL/min/1.73 m²; Q1, Q3 = first and third quartiles; SD = standard deviation; UPCR = urine protein to creatinine ratio, expressed as g/g.

Predictors of 2-Year Relapse in Univariable Analyses

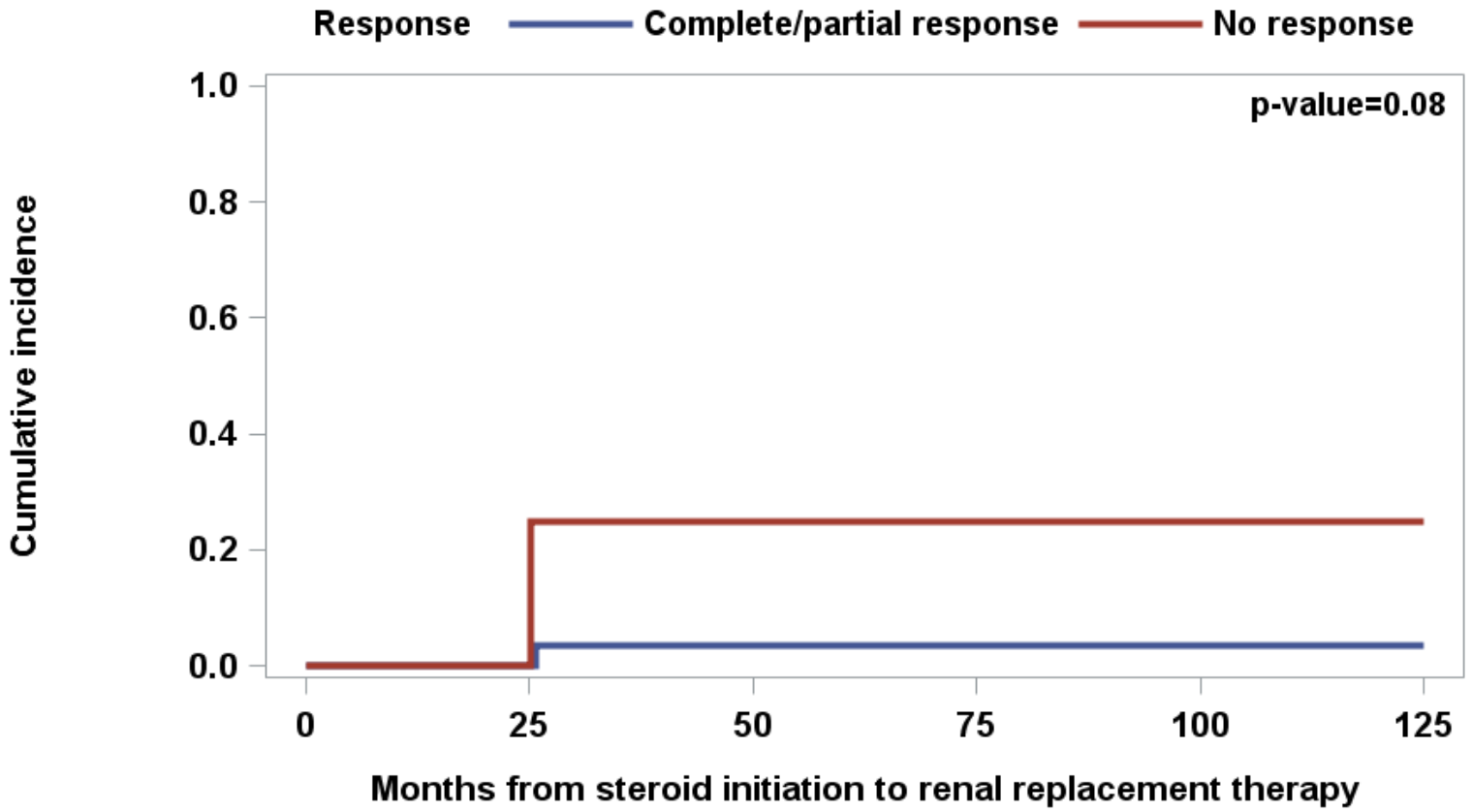
Parameter	Hazard ratio (95% CI)
Partial remission (ref = complete remission)	0.93 (0.27-3.19)
Female sex (reference = male)	2.07 (0.74-5.79)
Racial minority[a] (reference = White/Caucasian and non-Hispanic/Latino ethnicity)	0.60 (0.23-1.60)
Age at biopsy (reference = 18-44)	
45-64	0.62 (0.22-1.71)
65+	0.83 (0.23-3.02)
eGFR at biopsy (per 10-unit increase)	1.04 (0.88-1.22)
UPCR at biopsy (per doubling of UPCR)	1.02 (0.79-1.31)

- No statistically significant predictors of relapse were identified.
  - Estimates were generally imprecise given the small sample size.
- Results for multivariable analyses were very similar.

[a] Individuals with race listed as Asian, African American or Black, or Multiracial or ethnicity listed as Hispanic/Latino were combined to represent the "Racial minority" category. Individuals who had missing race *and* ethnicity data were classified as having missing information and were not included in the model.

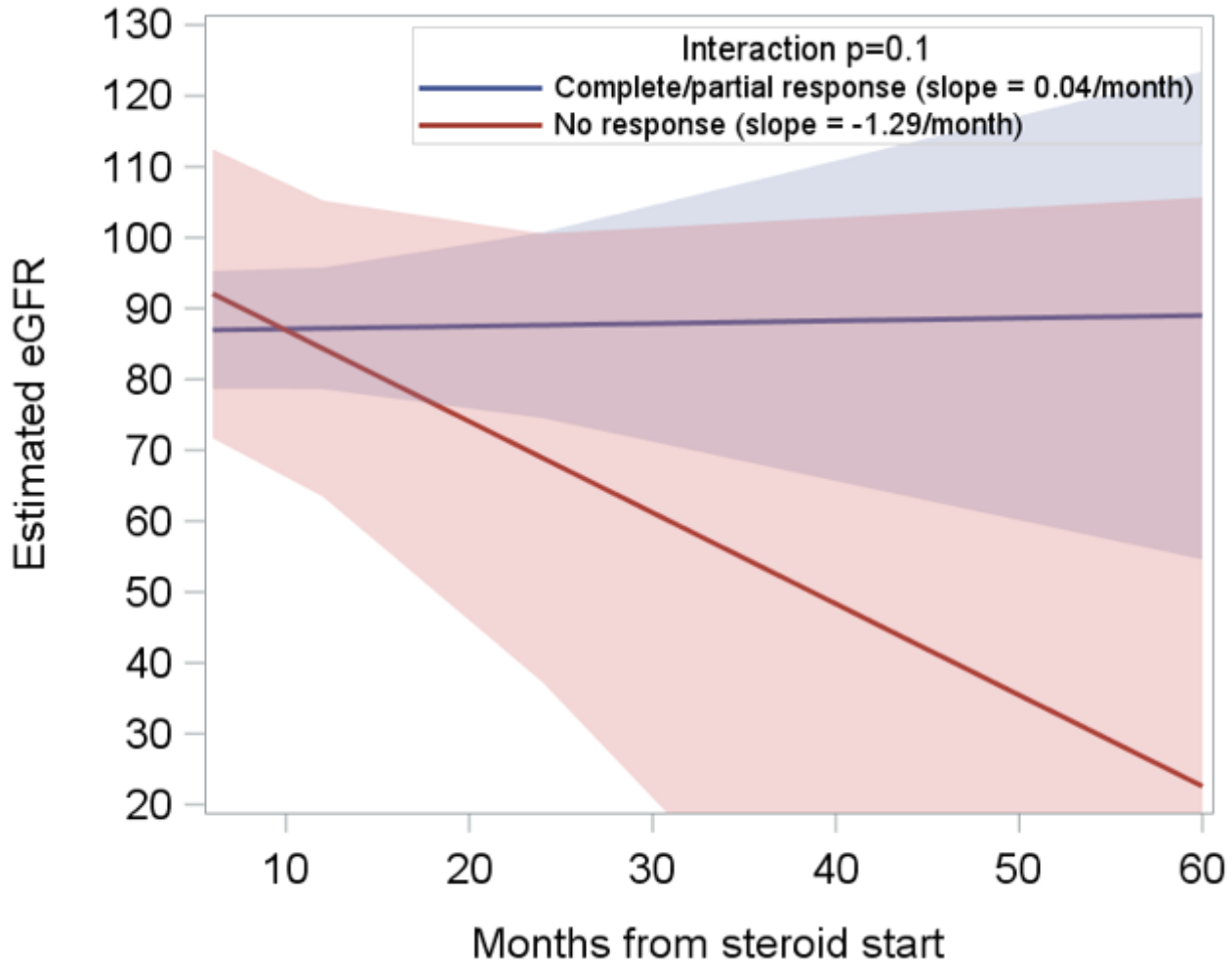
CI = confidence interval; eGFR = estimated glomerular filtration rate, expressed as mL/min/1.73 m²; Q1, Q3 = first and third quartiles; SD = standard deviation; UPCR = urine protein to creatinine ratio, expressed as g/g.

Time From Corticosteroid Initiation to Renal Replacement Therapy



Complete/partial response	31	28	15	7	4	1
No response	4	4	3	2	1	0

Change in eGFR Over Time by Corticosteroid Response Status



- Analyses included participants with at least 2 eGFR measurements and 1 year of follow-up.
  - 28 of 35 participants were eligible for these analyses:
    - 24 complete/partial responders
    - 4 nonresponders
- These are crude eGFR slopes.

Note: shaded regions represent 95% confidence intervals.
eGFR = estimated glomerular filtration rate, expressed as mL/min/1.73 m²;