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Enclosure:

- POSTER: A. Khan, B. Lewing, M. Helmuth et al. Presented at: American Society of Nephrology (ASN) Annual Meeting, October 22-25, 2026; Denver, CO, USA

FR-PO0669

A Registry-Based Study of Treatment Patterns and Outcomes in Patients With Focal Segmental Glomerulosclerosis in the United States

Anam M. Khan, PhD[1]; Benjamin Lewing, PhD[2,*]; Margaret Helmuth, MA[3]; J. Bradley Layton, PhD[1]; Saba Gidey, PharmD[2]; Caroline Demas, MPH[3]; Sergio Dellepiane, MD, PhD[2]; Laura Mariani, MD[3]
[1] RTI Health Solutions, Durham, NC, United States; [2] Otsuka, Princeton, NJ, United States; [3] University of Michigan, Ann Arbor, MI, United States
* Presenting author

Background

- Focal segmental glomerulosclerosis (FSGS) is a podocytopathy associated with nephrotic syndrome (NS)[1] that often leads to end-stage kidney disease and kidney failure–related death.
- Primary FSGS is likely immune mediated and often occurs without a known or obvious cause; it is less common than secondary or genetic forms of FSGS, especially in adults.[2,3]
- There remains an unmet need for effective therapies for FSGS and limited real-world evidence on treatment patterns, treatment response, relapse, and factors associated with these outcomes.

Objective

- To describe the real-world clinical characteristics, treatment patterns, and outcomes among adults with FSGS and nephrotic syndrome meeting study eligibility criteria.

Data Source

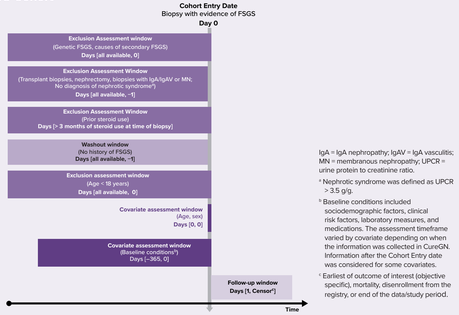
- CureGN Glomerular Disease Registry (CureGN)[4] is a prospective, non-interventional registry of patients with biopsy-confirmed glomerular diseases.
  - In the present study, only data from sites in the United States were used.
  - Registry enrollment began in 2014 and is ongoing.
- Study visits are scheduled to align with clinical care and enable sample collection at the time of disease exacerbation or remission.
  - Participants have a minimum of 1 in-person visit and biospecimen collection per year.

Methods

Study Design

- Registry-based, observational (non-interventional) cohort study.
- The Cohort Entry date was the date of the first biopsy showing evidence of FSGS that met the main study inclusion and exclusion criteria (**Figure 1**).
- Follow-up began the day after the Cohort Entry date and ended at registry disenrollment, end of available data, or death, whichever occurred first.

Figure 1. Variable Assessment Windows Relative to the Cohort Entry Date for the FSGS Cohort



IgA = IgA nephropathy; IgAV = IgA vasculitis; MN = membranous nephropathy; UPCR = urine protein to creatinine ratio.

[a] Nephrotic syndrome was defined as UPCR > 3.5 g/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.

Eligibility Criteria

Table 1. Summary of the Main Study Eligibility Criteria

Include ✓	Exclude ✗
Aged ≥ 18 years at the time of biopsy	Biopsy was of transplanted kidney
Enrolled in the registry within 1 year of their biopsy to allow for more complete capture of data	Have known genetic FSGS or conditions indicating secondary FSGS (diabetes, hepatitis C, sickle cell, obesity)
Evidence of NS (UPCR > 3.5 g/g)	Long-term corticosteroid use, meaning they had been using corticosteroids for longer than 3 months at the time of biopsy

Note: Additional eligibility criteria were applied for specific analyses.

Results

Cohort Creation

Figure 2. Cohort Creation and Key Findings

Individuals with FSGS
N = 74

Describe participants' characteristics at time of biopsy

- Mean (SD) age of participants was 47.2 (18.1) years.
- 64.9% were male; 35.1% were female.
- The majority (83.8%) of patients had at least 1 comorbidity.
- Median (Q1, Q3) eGFR was 53.1 mL/min/1.73 m² (30.3, 87.3), and UPCR was 6.0 g/g (3.6, 8.7).

Initiated treatment with corticosteroids
N = 42

Describe the initial immunosuppressive treatment option and time to treatment initiation within 1 year of biopsy

- 42 patients (57%) initiated corticosteroids within 1 year of biopsy.
  - 95% initially with steroids alone.
  - 5% with CNI or another immunosuppressant.
- Mean time from cohort entry to treatment initiation = 35 days (SD, 60).
  - 79% initiated within 6 weeks.
- Within 6 months of corticosteroid initiation, 50% had also used another immunosuppressant.
  - By 12 months, it was 69% (Figure 3).

See Figure 3

Corticosteroid-treated individuals with available UPCR measurements
N = 31

Complete remission N = 3 | **Partial remission N = 17** | **No response N = 11**

Describe treatment response
(Complete: UPCR < 0.3 g/g; Partial: < 50% of baseline, 0.3-3.5 g/g) based on UPCR measurements within 8 months of treatment initiation

- 20/31 patients (64.5%) responded.

Among Responders: 3/20 (15%) Complete remission; 17/20 (85%) Partial remission

- Characteristics of responders and non-responders are noted in Table 2.

See Table 2

Complete and partial responders with available follow-up UPCR values
N = 20

1-year relapse **70%** | 2-year relapse **75%**

Describe occurrence of relapse within 2 years of response; Evaluate predictors of relapse with Cox proportional hazards models

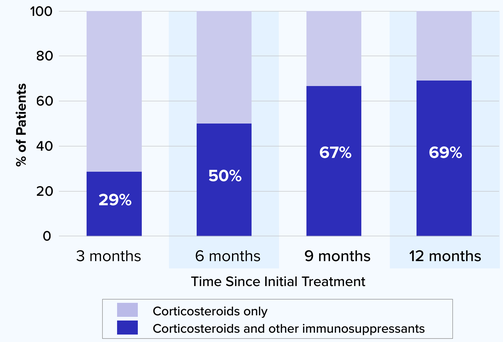
- 70.0% (14 patients) relapsed within 1 year after steroid response; 75.0% (15 patients) within 2 years.
- Relapse occurred in 13/17 partial responders (76.5%) and 2/3 complete responders (66.7%).
- The median (Q1, Q3) time to 2-year relapse among the 15 individuals who relapsed was 89.0 days (68.0, 154.0).

See Figure 4

CNI = calcineurin inhibitor; eGFR = estimated glomerular filtration rate; Q = quartile; SD = standard deviation.

Treatment Initiation

Figure 3. Treatment Patterns in Patients With FSGS Initiating Corticosteroids



Treatment Response

Table 2. Characteristics of Responders and Non-responders

Characteristic	Responders (complete or partial) (N = 20)	Non-responders (N = 11)
Baseline UPCR (g/g), median (Q1, Q3)	5.5 (4.1, 8.6)	8.2 (6.8, 10.1)
UPCR measurements (g/g) within 8 months of corticosteroid initiation, median (Q1, Q3)	4.0 (3.0, 6.0)	4.0 (1.0, 5.0)
Days from Cohort Entry to corticosteroid initiation, median (Q1, Q3)	9.5 (3.0, 65.0)	12.0 (5.0, 18.0)

- Responders had lower baseline UPCR and started initial treatment slightly sooner than non-responders (**Table 2**).
  - The median number of UPCR measurements was similar across responders and non-responders, suggesting that findings regarding time to response were not entirely attributed to testing frequency.

Disclosures

This study was funded by Otsuka. Funding for the CureGN consortium is provided by U24DK100845, U01DK100846, U01DK100876, U01DK100866, and U01DK100867 from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Patient recruitment is supported by NephCure.

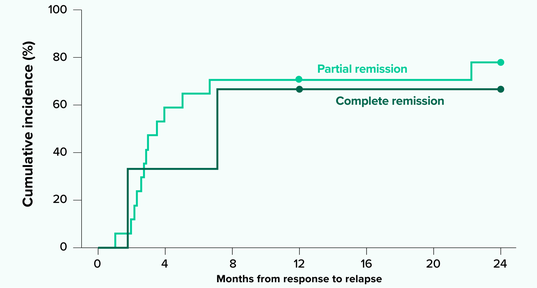
AMK and JBL are employees of RTI Health Solutions, which received funding from Otsuka for this study. BL, SG, and SD are employees of Otsuka, which funded the study. MH, CD, and LM are employees of the University of Michigan, which received funding from Otsuka for this study.

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Relapse

Figure 4. Time-to-Relapse in the 2 Years After Treatment Response by Remission Status



Complete remission	3	2	1	1	1	1	1
Partial remission	17	7	5	5	5	4	3

- In exploratory univariate analysis, older age (45-64 years vs. 18-44 years) was associated with relapse in the 1 and 2 years after response (1-year relapse: hazard ratio [HR], 5.52 [95% confidence interval [CI], 1.42-21.38]; 2-year relapse: HR, 5.35 [95% CI, 1.40-20.44]), although confidence intervals were wide.
  - Response status (partial or complete) was not associated with relapse in univariate or multivariate models.

Study Strengths and Limitations

Strengths	Limitations
Real-world, longitudinal registry data collected in routine clinical practice.	The small sample size for some analyses resulted in wide CIs, requiring estimates to be interpreted with caution.
Routine clinical visit records enabled the collection of rich demographic, clinical, lifestyle, and outcomes data while also considering participant-reported outcomes.	Some individuals lacked genetic information (exclusion criteria) and were assumed not to have genetic FSGS.
Laboratory data collected during routine clinical care were captured in the registry.	There was limited information on FSGS subtype (e.g., primary FSGS).
The longitudinal nature of data allowed for the study of outcomes over time.	Response and relapse ascertainment depended on availability and timing of clinically collected UPCR measurements.

Conclusions

- More than half of adults with FSGS initiated corticosteroids within 1 year of biopsy, with most initiators starting treatment within 6 weeks.
- Among corticosteroid-treated adults with FSGS and evaluable UPCR, approximately two-thirds achieved a response, but complete remission was uncommon.
- Subsequent relapse was frequent, with 75% of responders relapsing within 2 years.
- Together, frequent relapse and use of additional immunosuppression highlight the challenge of achieving sustained disease control and the need for treatment approaches that achieve more durable remission.

Contact: Benjamin Lewing, PhD; Otsuka
Benjamin.Lewing@otsuka-us.com

Presented at: American Society of Nephrology Kidney Week 2026; 22-24 October 2026

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