Focal Segmental Glomerulosclerosis (FSGS) In Adults: A Retrospective Analysis Of US Prevalence And Impacts Of Proteinuria And Kidney Function Decline On Healthcare Resource Utilization (HRU) And Costs

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RESULTS

Baseline characteristics

- The prevalence cohort consisted of 9,899 patients; mean age 47.9 years (93.6% aged ≥18 years), 43.1% female and 58.4% Caucasian. Mean proteinuria was 4.2 g/g and evidence of nephrotic range proteinuria* was observed in 17.6% of patients, mean estimated glomerular filtration rate (eGFR) was 45.8 mL/min/1.73 m², and 68.9% had CKD stage 3–5 (Table 1). Among patients with available data, 63% had proteinuria >1.5 g/g and 38% had proteinuria ≥3.5 g/g at baseline.

- The HRU/cost cohort consisted of 1,082 adult patients (aged ≥18 years) with linked claims data; mean age 50.7 years, 42.9% female and 59.1% Caucasian. Mean proteinuria was 3.7 g/g, evidence of nephrotic range proteinuria* was observed in 15.6% of patients, mean eGFR was 42.7 mL/min/1.73 m², and 72.5% had CKD stage 3–5 (Table 1).

Table 1. Baseline demographic and clinical characteristics

	Prevalence (n=9,899)	HRU/Cost (n=1,082)
Age, Mean (SD), years	47.9 (18.6)	50.7 (15.8)
Age, n (%)		
≥18 years	9,261 (93.6)	1,082 (100.0)
Gender, n (%), Female	4,262 (43.1)	464 (42.9)
Ethnicity, n (%), Not Hispanic	7,952 (80.3)	876 (81.0)
Race, n (%)		
Caucasian	5,780 (58.4)	639 (59.1)
African American	2,650 (26.8)	294 (27.2)
Asian	337 (3.4)	37 (3.4)
Insurance type, n (%)		
Commercial	4,461 (45.1)	584 (54.0)
Medicare	3,023 (30.5)	281 (26.0)
Medicaid	1,850 (18.7)	177 (16.4)
Proteinuria, g/g, mean (SD)	4.2 (6.8)	3.7 (4.3)
Nephrotic range proteinuria,* n (%)	1,741 (17.6)	169 (15.6)
eGFR, mean (SD)	45.8 (39.4)	42.7 (30.7)
CKD stage, n (%)		
Stage 1	1,010 (10.2)	76 (7.0)
Stage 2	987 (10.0)	122 (11.3)
Stage 3	2,379 (24.0)	322 (29.8)
Stage 4	1,734 (17.5)	197 (18.2)
Stage 5/ESKD	2,715 (27.4)	265 (24.5)
Unknown	1,074 (10.8)	100 (9.2)
Charlson Comorbidity Index, mean (SD)	1.9 (1.8)	1.8 (1.5)
Any CV event, n (%)	400 (4.0)	54 (5.0)

*Pediatrics (1–18 years): UP/C ≥2 g/g; Adults (>18 years): UP/C >3.5 g/g or 24-hour urine protein ≥3.5 g/day. Denominator includes patients without proteinuria data.

Prevalence of FSGS in the United States

- Among patients of all ages, the average annual estimated standardized prevalence of FSGS in the US (2016-2020) was 212.26 per 1,000,000 based on US Census Bureau data (Table 2)

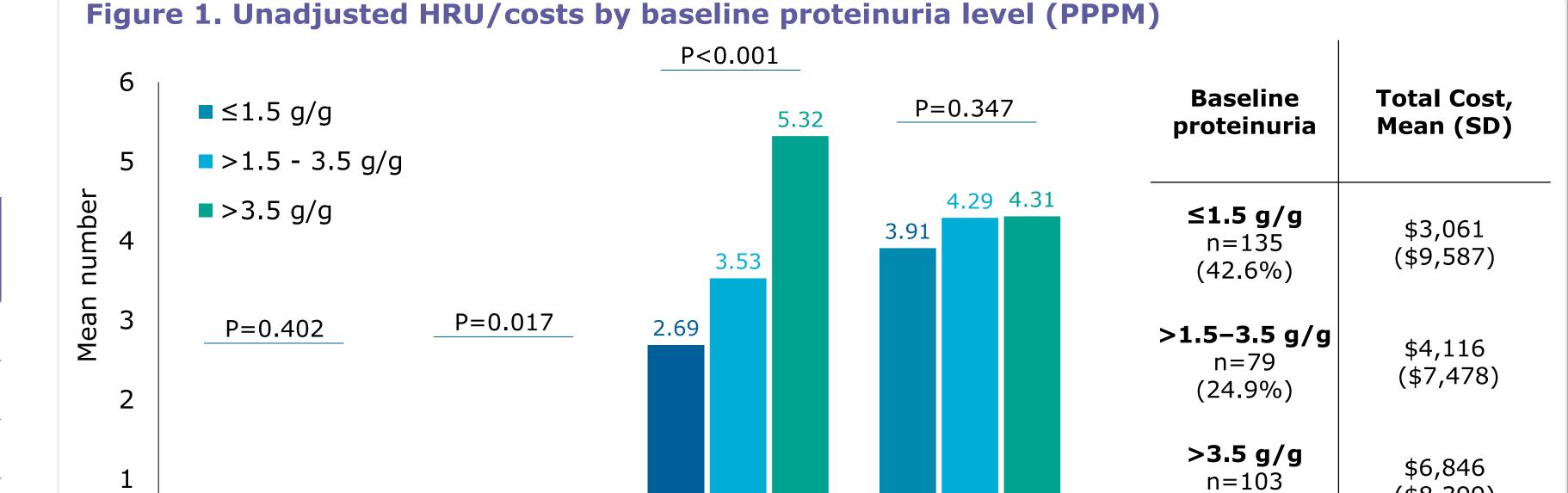### Table 2. Standardized prevalence

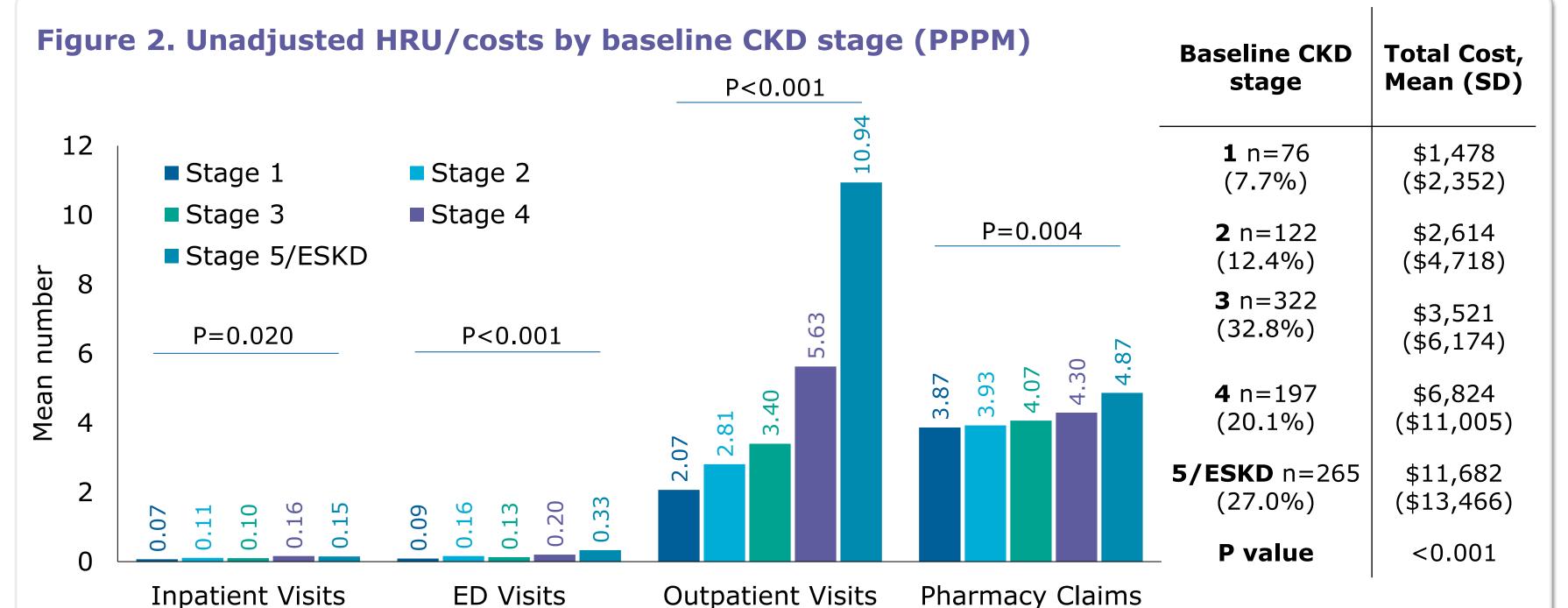| Year	Standardized prevalence per 1,000,000 US population (95% CI)
2016	158.03 (139.03, 179.42)
2017	191.03 (170.34, 214.06)
2018	223.23 (199.87, 249.19)
2019	228.97 (205.04, 255.60)
2020	260.05 (231.30, 292.34)

Unadjusted HRU/costs among adults with FSGS by baseline proteinuria level

- Among adult patients with baseline proteinuria data, 57.4% had high levels of proteinuria at baseline (24.9% >1.5 – 3.5 g/g and 32.5% >3.5 g/g) (Figure 1)

- HRU was significantly higher among adult patients with baseline proteinuria levels >3.5 g/g; (≤1.5 [n=135] vs >1.5–3.5 [n=79] vs >3.5 g/g [n=103]; emergency department (ED) visits (PPPM), 0.12 vs 0.16 vs 0.23 (P=0.017); outpatient visits (PPPM), 2.69 vs 3.53 vs 5.32 (P<0.001) (Figure 1)

- Mean total costs (PPPM) were also significantly higher for adult patients with a higher severity of proteinuria; $3,061 (≤1.5 g/g) vs $4,116 (1.5–3.5 g/g) vs $6,846 (>3.5 g/g); p=0.001) (Figure 1)

Unadjusted HRU/costs among adults with FSGS by baseline CKD stage

- Higher CKD stage at baseline was associated with significantly higher PPPM inpatient visits (P=0.020), ED visits (P<0.001), outpatient visits (P<0.001) and pharmacy claims (P=0.004) (Figure 2)

- Mean total costs PPPM increased significantly with higher CKD stage (P<0.001) (Figure 2)

Figure 1. Unadjusted HRU/costs by baseline proteinuria level (PPPM)

Baseline proteinuria	Total Cost, Mean (SD)
≤1.5 g/g n=135 (42.6%)	$3,061 ($9,587)
>1.5–3.5 g/g n=79 (24.9%)	$4,116 ($7,478)
>3.5 g/g n=103 (32.5%)	$6,846 ($8,399)
P value	0.001

Figure 2. Unadjusted HRU/costs by baseline CKD stage (PPPM)

Baseline CKD stage	Total Cost, Mean (SD)
1 n=76 (7.7%)	$1,478 ($2,352)
2 n=122 (12.4%)	$2,614 ($4,718)
3 n=322 (32.8%)	$3,521 ($6,174)
4 n=197 (20.1%)	$6,824 ($11,005)
5/ESKD n=265 (27.0%)	$11,682 ($13,466)
P value	<0.001

CONCLUSIONS

▷ Increasing prevalence of FSGS was observed between 2016 and 2020, which may indicate better disease awareness

▷ Higher severity of proteinuria (>1.5 g/g or >3.5 g/g) and worsening kidney function were associated with higher costs and HRU among patients with FSGS in the US

▷ Treatments that reduce proteinuria and slow the rate of decline in kidney function have the potential to reduce the resource intensity and economic burden of FSGS

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ABBREVIATIONS

CI, confidence interval; CKD, chronic kidney disease; CKF, chronic kidney failure; ED, emergency department; eGFR, estimated glomerular filtration rate; EHR, electronic health record; ESKD, end-stage kidney disease; FSGS, focal segmental glomerulosclerosis; HRU, healthcare resource utilization; NLP, natural language processed; PPPM, per-patient-per-month; SD, standard deviation; USD, United States Dollars

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INTRODUCTION

- In the US, FSGS is a leading cause of kidney failure and, if not controlled, FSGS-associated glomerular disease often follows a progressive course to End Stage Kidney Disease (ESKD) or End Stage Renal Disease, also called chronic kidney failure (CKF)[1-3]

- Persistent podocyte injury leads to proteinuria and a progressive decline in glomerular filtration rate[3-5]

- Few studies have reported the prevalence of FSGS in the US, or the HRU/costs associated with FSGS

Objectives

- Estimate the prevalence and profile of patients with FSGS in the US population

- Describe FSGS patient characteristics

- Estimate all-cause HRU and costs for patients with FSGS stratified by proteinuria level (≤1.5 g/g vs >1.5-3.5 g/g vs >3.5 g/g) and chronic kidney disease (CKD) stage

METHODS

Study design and data source

- Descriptive, retrospective analysis based on Optum® de-identified Market Clarity and proprietary natural language processed (NLP) Data. The Optum® de-identified Market Clarity Dataset deterministically links medical and pharmacy claims with electronic health record (EHR) data from providers across the care continuum.

- Study period: January 01, 2006 – March 31, 2021

- Identification period: July 01, 2006 – March 31, 2021 (index identification period)

- Baseline period: 6 months prior to index

- Index date: first FSGS ICD-10 diagnosis code or NLP term within the identification period

- All costs were normalized/discounted and adjusted to 2020 USD using the Consumer Price Index and reported as per patient per month (PPPM) values

- ESKD defined as: first evidence of CKD stage 5 (eGFR<15 mL/min/1.73 m² or ICD-10: N18.5), kidney transplant procedure, dialysis

Statistical analysis

- Categorical and continuous variables were summarized using descriptive statistics. Standardized prevalence was estimated using direct standardization method. HRU/costs by proteinuria and CKD stage were assessed using generalized linear models.

Inclusion criteria (prevalence and HRU/cost)

- Patients with at least two NLP term entries with "focal_segmental_glomerulosclerosis" or "segmental glomerulosclerosis" AND/OR FSGS-associated ICD-10 diagnosis codes (N03.1, N04.1, N05.1, N06.1, N07.1), within 180 days at least 30 days apart

- Patients with negation terms in relation to the FSGS NLP term were excluded (negation terms: 'deny', 'failed', 'ignore', 'n/a', 'negative', 'question', 'reject', 'rule out', 'uncertain', 'unspecified')

Inclusion criteria (HRU/cost)

- >6 months pre-index continuous enrollment (baseline)

- >6 months post-index continuous enrollment (follow-up)

- Patients with linked Optum Market Clarity claims data

Exclusion criteria (HRU/cost)

- Cancer diagnosis pre- or post-index
- Pregnancy pre-index
- COVID-19 pre- or post-index

Methods updates since abstract submission

- Study period extended from March 31, 2020 to March 31, 2021

- Denominators for prevalence calculations were updated to align with method used for patient identification (i.e., only including patients with activity captured by claims or EHR)

DISCUSSION

- A majority of patients with FSGS had a higher severity of proteinuria (>1.5 g/g or >3.5 g/g) which was associated with a greater HRU and cost burden

- Declining kidney function (measured as advancing CKD stage) was associated with significantly higher HRU and total costs

Limitations

- This study was limited to patient data in Optum Market Clarity and may not be representative of the US population with FSGS

- Optum applies standard pricing algorithms to account for differences in pricing across health plans and provider contracts with resulting cost information designed to reflect allowed payments for all provider services across regions

- Missing data or errors in detection of FSGS-related terms and codes in patient records may introduce bias into the analyses including potential underestimation of US prevalence. Included patients with FSGS-related NLP terms may have more severe disease and bias the study results.

- The cost data provide a partial view of economic burden as out-of-pocket costs to patients were not included

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