

A USRDS Retrospective Cohort Study: Epidemiology, Treatment Modalities, and Burden of End-Stage Kidney Disease Attributed to Focal Segmental Glomerulosclerosis (FSGS)

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CONCLUSIONS

FSGS-attributed ESKD in the US is associated with a substantial burden to patients and the healthcare system

There is a high unmet medical need for FSGS treatments that delay or prevent the need for dialysis and/or transplantation and reduce the risk of death

DISCLOSURES

Mark Bensink is the managing director of Benefit Consulting which received consulting fees from Traverse Therapeutics, Inc. Deborah Goldschmidt, Riley Taiji, and Zheng-Yi Zhou are employees of Analysis Group, which received consulting fees from Traverse Therapeutics, Inc. Kaijun Wang is an employee of Traverse Therapeutics, Inc. and has an equity or other financial interest in Traverse Therapeutics, Inc. Richard Lieblich is an employee of VJA Consulting, which received consulting fees from Traverse Therapeutics, Inc. Martin Bunke is the director of CM Bunke Consulting, which received consulting fees from Traverse Therapeutics, Inc.

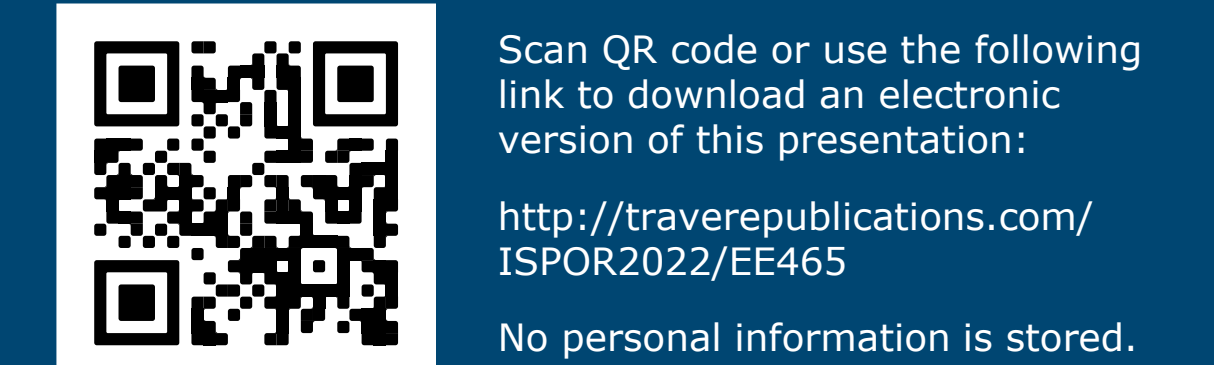
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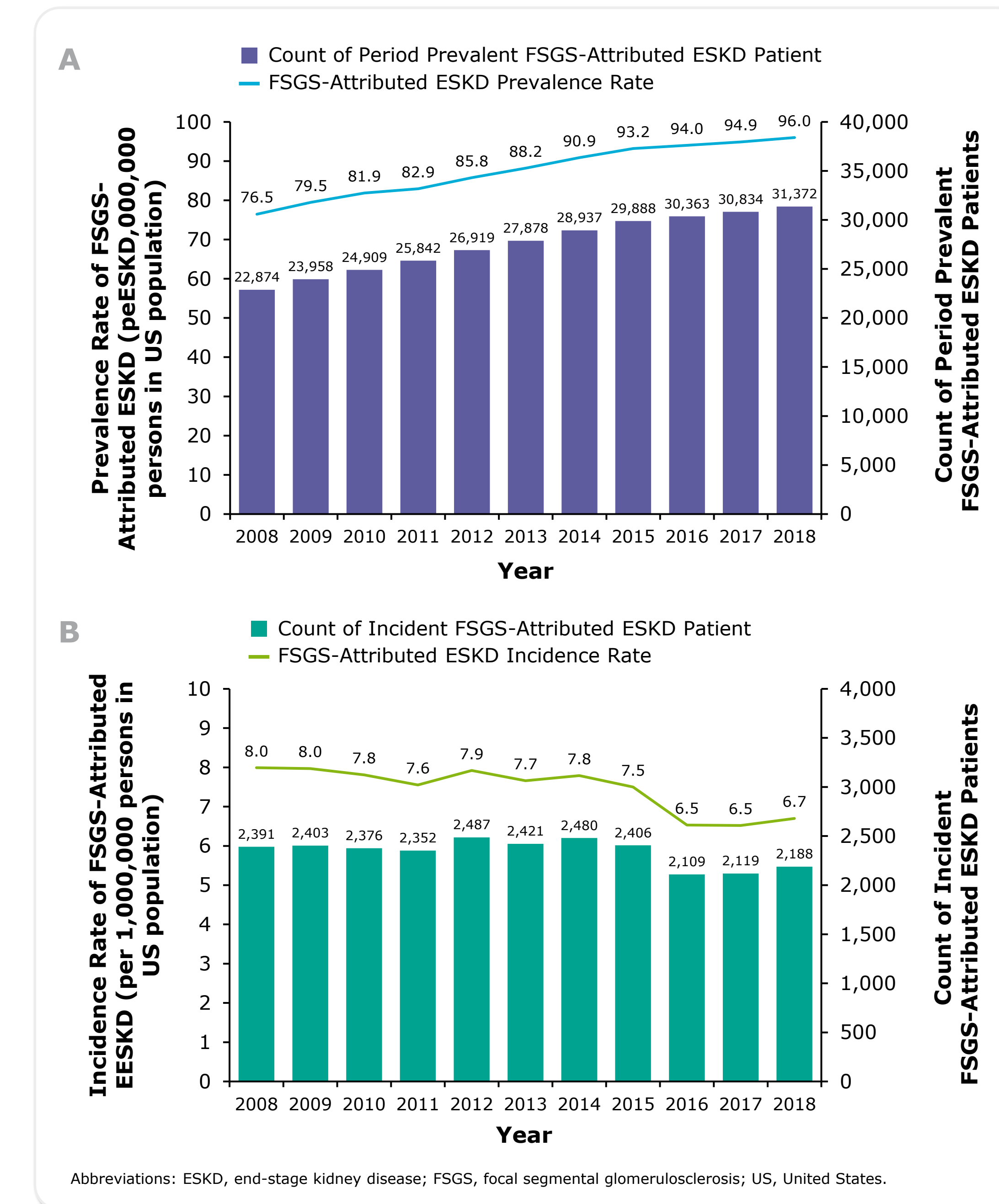
TRAVERE THERAPEUTICS

RESULTS

Epidemiology Results

- From 2008-2018, an average of **2,339** FSGS patients were diagnosed with ESKD annually with approximately **27,600** prevalent FSGS-attributed ESKD patients each year
- The average annual incidence and prevalence rates were **7.4** and **87.6** per million in the US population, respectively

Figure 1. Prevalence and Incidence of FSGS-Attributed ESKD



Patient Characteristics

- 25,699 patients with FSGS-attributed ESKD were included in the analyses
- At ESKD registration, median age was 53 years; 61% were male; 62% and 33% were White and Black, respectively

Table 1. Patient Characteristics

Demographic Characteristics	FSGS-Attributed ESKD Patients (n=25,699)
Age as of the Index Date, mean ± SD [median]	51.0 ± 18.9 [52.6]
Male, n (%)	15,788 (61.4%)
Race, n (%)	
White	15,886 (61.8%)
Black	8,373 (32.6%)
Asian	994 (3.9%)
Native Hawaiian or Other Pacific Islander	201 (0.8%)
American Indian/Alaska Native	144 (0.6%)
Other	101 (0.4%)
Employment Status 6-Months Prior to Index, n (%)	
Retired	8,975 (34.9%)
Employed Full-time	8,099 (31.5%)
Unemployed	5,008 (19.5%)
Student	1,388 (5.4%)
Employed Part-time	1,381 (5.4%)
Other Employment Status	848 (3.3%)
Medical Coverage as of the Index Date*, n (%)	
Employer Group Health Insurance	9,666 (37.6%)
Medicare Coverage	9,008 (35.1%)
Medicaid Coverage	5,794 (22.5%)
Other Medical Insurance	5,017 (19.5%)
No Medical Insurance	1,840 (7.2%)
Medicare Advantage	1,377 (5.4%)
Clinical Characteristics	
eGFR (mL/min/1.73m²)*, mean ± SD [median]	9.0 ± 6.4 [8.1]
Comorbidities as of the Index Date*, n (%)	
History of Hypertension	22,539 (87.7%)
Diabetes	4,604 (17.9%)
Congestive Heart Failure	3,142 (12.2%)

*Patients may have had multiple types of medical coverage. *Estimated glomerular filtration rate (eGFR) was calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation and reported directly in the Medical Evidence file of the USRDS data. **The top 3 comorbidities are shown.

Treatment Modalities

- The mean [median] follow-up time of FSGS-attributed ESKD patients was **54.4 [49.4] ± 36.8 months**
- 93%** of patients started on dialysis, mostly in-center hemodialysis. Patients spent an average of **3.3 years** on dialysis; this was impacted by patients receiving a kidney transplant and patient mortality
- 7%** of patients received a kidney transplant at ESKD registration. Over the entire study period, **33%** of FSGS-attributed ESKD patients in the USRDS database received a kidney transplant

Data Source

- US Renal Data System (USRDS) is the national data registry that collects, analyzes, and distributes information on the ESKD population in the US, including treatments and outcomes. All ESKD patients, regardless of insurance coverage and age, are included in the USRDS database
- Linked information on HRU is available for ESKD patients with Medicare coverage
- This study included USRDS data from 2008–2018

Sample Selection

- Patients registered to the USRDS with FSGS as the primary cause of ESKD in 2008–2018 were identified using ICD-9-CM code **582.1** and ICD-10-CM codes **N03.1**, **N04.1**, and **N05.1** (see limitations section for details)
- The *index date* was defined as the date of ESKD registration (i.e., in the USRDS data, the earliest date of first dialysis or transplant)
- The *follow-up period* was defined as the period from the index date until death, loss to follow-up, or end of data availability, whichever came first
- For the *Medicare subgroup*, patients were required to have at least 1 year of continuous medical coverage (i.e., Medicare Part A and B) following the index date

Statistical Methods

Epidemiology

- Prevalence and incidence estimates for FSGS-attributed ESKD in the US were calculated on a per 1,000,000 persons per year basis from 2008–2018
- Prevalence was estimated as the number of FSGS-attributed ESKD patients who were alive and whose index dates occurred before the reporting year, divided by the size of the US population
- Incidence was estimated as the number of FSGS-attributed ESKD patients whose index dates occurred during the reporting year, divided by the size of the US population

Patient Characteristics

- Demographics, laboratory values, and comorbidities as reported at USRDS registration were summarized with descriptive statistics, consisting of means, medians, and standard deviations (SDs) for continuous variables, and frequency counts and proportions for categorical variables

Figure 2. Treatment Modalities Throughout the Study

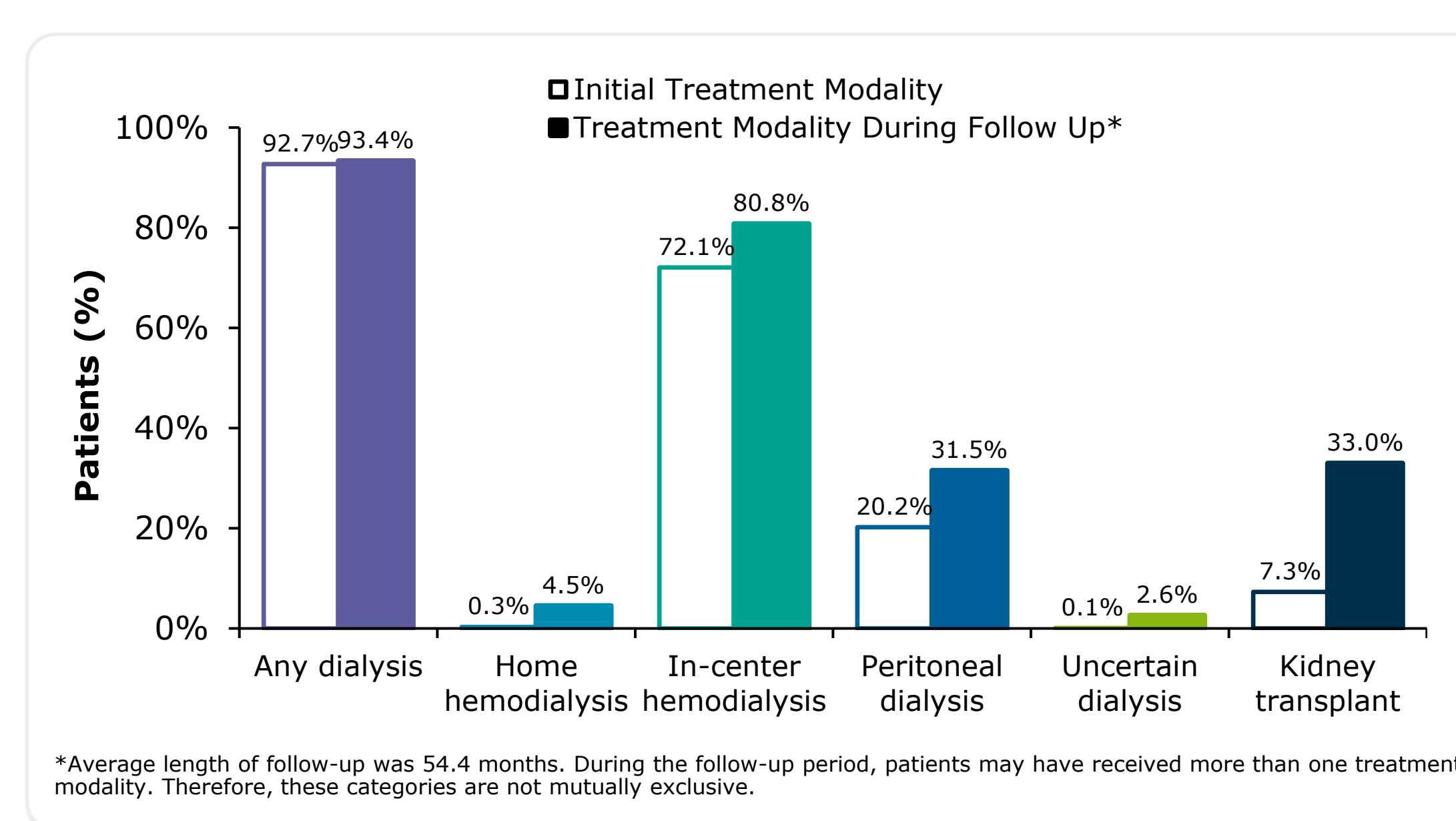


Figure 3A. Clinical Outcomes (KM Analysis) – Time to Transplant

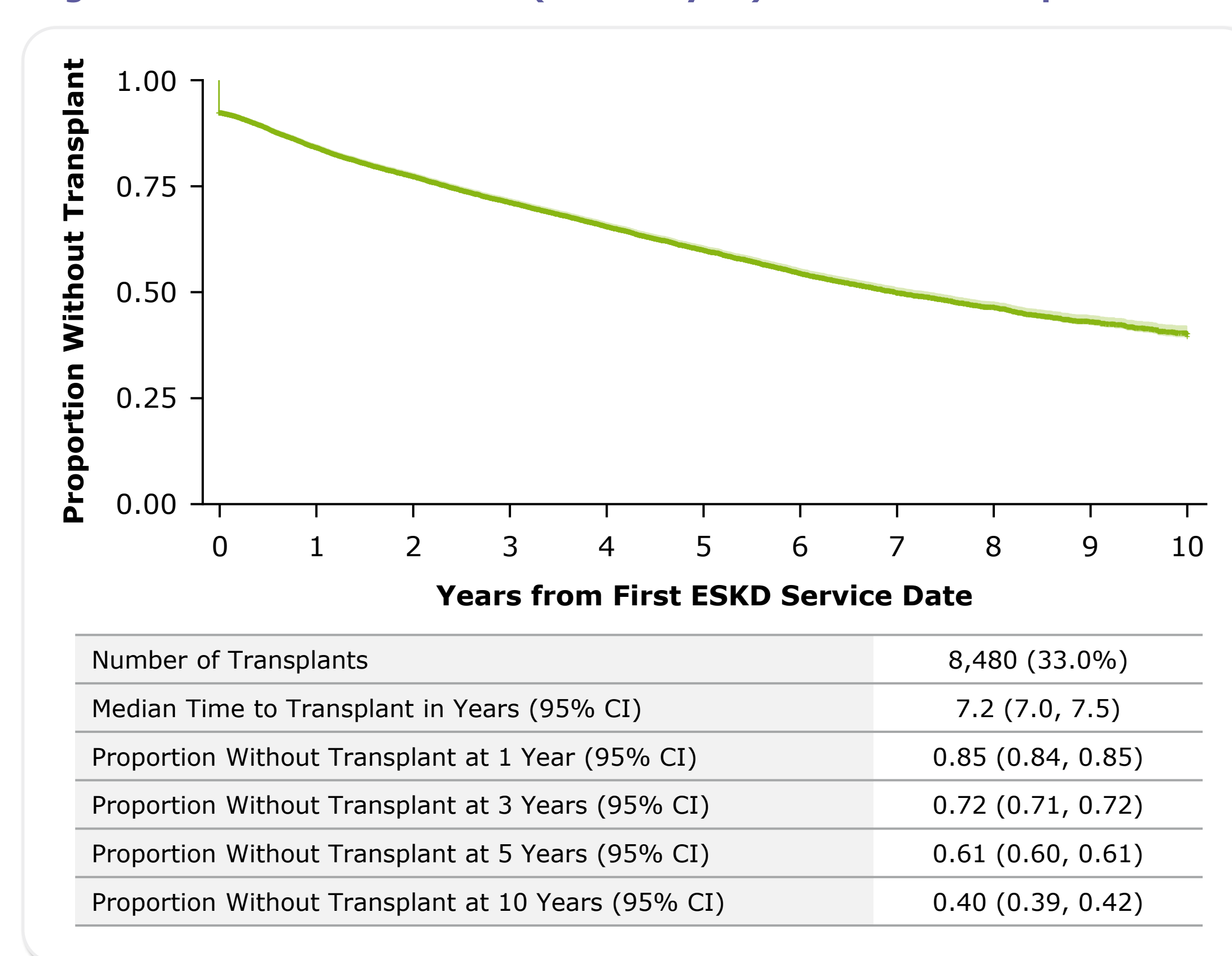


Figure 3B. Clinical Outcomes (KM Analysis) – Overall Survival

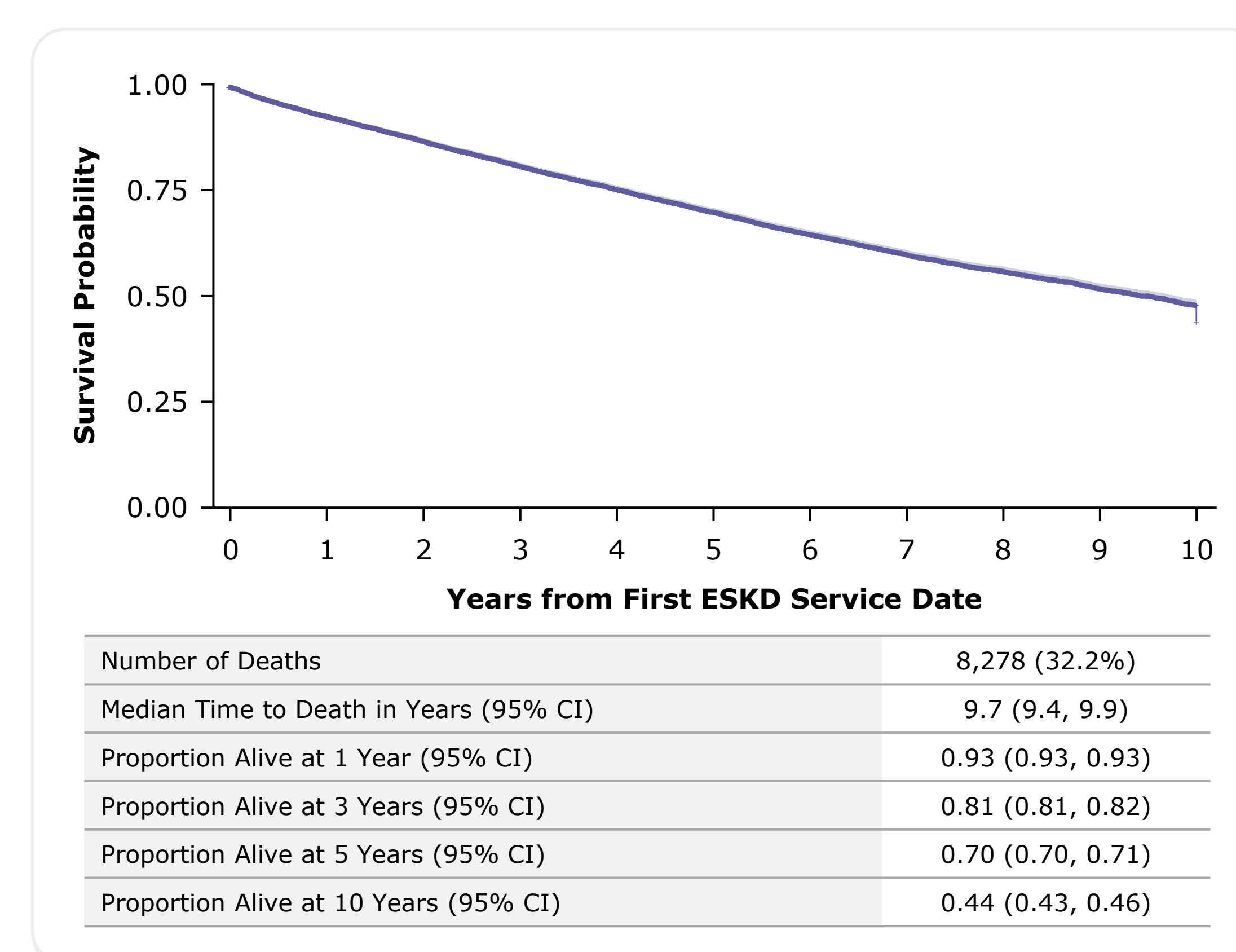


Table 2. HRU During the 1 Year Following USRDS Registration*

FSGS-Attributed ESKD Medicare Subgroup (n=5,575)	Proportion with ≥1 Visit n (%)	Number of Visits* Mean ± SD [median]
Inpatient Admissions	4,139 (74.2%)	2.0 ± 2.3 [1]
<i>Inpatient Length of Stay* (Days)</i>	–	22.3 ± 40.8 [7]
Outpatient Visits	5,475 (98.2%)	30.9 ± 18.0 [29]
Emergency Room Visits	3,753 (67.3%)	2.4 ± 3.67 [1]
Home Health Agency Visits	3,113 (55.8%)	4.4 ± 7.28 [1]
Skilled Nursing Facility Visits	641 (11.5%)	5.2 ± 25.5 [0]
Hospice	26 (0.5%)	0.5 ± 9.4 [0]

*HRU was assessed for the 5,575 patients in the Medicare subgroup. *Number of visits was calculated among all patients in the Medicare subgroup. *Inpatient length of stay was calculated among patients in the Medicare subgroup with at least 1 inpatient admission.

INTRODUCTION

- Focal segmental glomerulosclerosis (FSGS) is a histologic pattern of glomerular injury reported in patients who present with proteinuria, chronic kidney disease, and sometimes nephrotic syndrome.¹ FSGS may be primary (i.e., not secondary to another condition or due to genetic mutation) or secondary (e.g., viral- or drug-induced causes as well as conditions mediated by adaptive structural-functional responses to glomerular hypertension such as systemic hypertension, obesity, sickle cell anemia, kidney allograft, aging kidney).^{2,3}
- FSGS places a large clinical burden upon patients by severely reducing their kidney function as the disease progresses, which may lead to end-stage kidney disease (ESKD), also called chronic kidney failure (CKF),⁴ over time⁵
- ESKD also poses significant economic burden to healthcare systems around the world, largely due to high costs associated with dialysis and transplantation.^{6,7}
- Currently, there are no FDA-approved drug therapies specifically for FSGS
- Real-world evidence on prevalence and incidence rates, patient characteristics, treatment modalities, clinical outcomes, and healthcare resource utilization (HRU) related to FSGS-attributed ESKD is lacking

Objective

- This retrospective observational study aimed to describe the prevalence and incidence rates, patient characteristics, treatment modalities, clinical outcomes, and HRU related to FSGS-attributed ESKD in the US

METHODS

DISCUSSION

Treatment Modalities

- The types of dialysis and/or kidney transplant incurred by FSGS-attributed ESKD patients, at and after the index date, were summarized as frequency counts and proportions

Clinical Outcomes

- Time to kidney transplant and time to death were assessed from index date through the follow-up period using Kaplan-Meier (KM) analyses
- Median times to kidney transplant and overall survival were reported with associated 95% confidence intervals (CIs)

Health Resource Utilization

- Among the *Medicare subgroup*, all-cause HRU was summarized in the one-year period after the index date, stratified by place of service
- Frequency counts and proportions of patients with ≥1 visit in each HRU category were reported; means, medians, and SDs of the number of visits were reported by HRU category

- The prevalence of FSGS-attributed ESKD has risen steadily over 10 years from 2008 to 2018
- These data show that patients in the USRDS database with FSGS-attributed ESKD rely more on dialysis as treatment than kidney transplant, with only 33% receiving a transplant over the entire study period, comparable to 30% in the general prevalent ESKD population;⁸ more than half of the patients died within 10 years
- Healthcare resource use is high for this population; among patients with Medicare claims data, 74% required hospitalization and 67% visited the emergency room in the first year after USRDS registration, and the mean number of outpatient visits was >30 per patient per year

Limitations

- Patients are included in the USRDS registry if they receive treatment for ESKD (dialysis or transplant); as such, for this study (and all studies using USRDS data), ESKD should be interpreted as “treated ESKD”
- Analyses of HRU are limited to patients with Medicare coverage for the 12-month period following the index date. Patients with Medicare as of the index date are more likely to be aged 65 or older; their HRU may not be representative of the general FSGS-attributed ESKD population
- When registering a patient with ESKD, physicians fill out a Medical Evidence Report form, which includes a field for the primary cause of kidney failure using ICD-9-CM (for patients from 1995 to mid-2015) or ICD-10-CM (mid-2015 onward) codes. The forms used from 1995 until mid-2015 provided disease names and ICD-9-CM codes to choose from, while the forms used from mid-2015 until 2018 did not. This may have led to under-reporting of FSGS starting in mid-2015 if there was uncertainty among physicians about which codes to use.
- The analyses include all patients with FSGS as the primary cause of ESKD, as reported by the registering physician, and can not separate patients with primary or secondary FSGS