Focal segmental glomerulosclerosis: prevalence, risk factors, and outcome among kidney transplant recipients: Kuwait experience

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Background
Posttransplant focal segmental glomerulosclerosis (FSGS) is a major risk factor for graft loss. We therefore aimed to assess patients with FSGS in our cohort of kidney transplant recipients (KTR).

Methods
In this retrospective study, kidney transplant recipients (KTR) between 1996 and 2020 were screened for the diagnosis of FSGS, and details were recorded about the transplant, clinical outcomes, treatments, and other risk factors.

Results
Among 3221 KTR screened, 109 (3.38%) were identified to have FSGS as original kidney disease. Of them, 57 (52.3%) had a diagnosis of idiopathic FSGS. Most of patients were Kuwaiti males who received their grafts from living donors (82.5 vs. 92.3% in the secondary group). All patients were maintained on calcineurin inhibitors and more than 40% were on angiotensin-receptor blockers or angiotensin-converting enzyme inhibitors without significant difference between the recurrent or nonrecurrent groups ($P > 0.05$). FSGS recurred in 10 patients (17.5%) which was significantly associating sensitization against tuberculosis. Most patients with recurrent FSGS received plasma exchange (70 vs. 36.2%, $P = 0.049$) and rituximab (70 vs. 23.4%, $P = 0.004$) compared to the group without recurrence, respectively. Follow up laboratory parameters showed significantly higher mean serum creatinine after 6 months onwards ($P < 0.05$), significantly higher proteinuria after 3 months onwards ($P < 0.05$) and significantly lower mean plasma albumin at third and 12th months of follow up ($P < 0.05$). However, the graft outcome was comparable in the two groups ($P > 0.05$).

Conclusions
Lower rate of recurrence of idiopathic FSGS in our cohort (17.5%) and the comparable patient and graft outcomes might be due to the optimized immunosuppressive regimen. The key novel finding is the significant association between sensitization against tuberculosis and the recurrence of primary FSGS, suggesting a potential role of a pre-existing immune-sensitized state that will need further evaluation on a larger scale.

Keywords:
focal segmental glomerulosclerosis, kidney transplant, recurrence

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Introduction

Focal segmental glomerulosclerosis (FSGS) recurrence among kidney transplant recipients (KTR) is a significant concern due to its impact on graft survival and patient morbidity. Studies have highlighted various aspects of this condition, including its prevalence, risk factors, outcomes, and potential treatments.

FSGS recurrence in adult KTRs occurs at a notable rate, with up to 30% of recipients experiencing recurrence [1]. Factors associated with an increased risk of recurrence include younger age, nonwhite ethnicity, and receiving a transplant from a live donor. Interestingly, grafts from live donors have shown significantly better median survival compared to those from deceased donors, despite the increased risk of recurrence [2]. The predicted incidence of FSGS recurrence after 7 years in recipients with primary FSGS is as high as 50% [3].

Recurrent FSGS leads to lower graft survival and increased morbidity in transplant recipients. Remission is possible with treatments such as plasmapheresis, and for those who do not respond or lose their graft, longer

treatment courses may be necessary [4]. Tiredness and swelling are common symptoms associated with recurrent FSGS [5]. Abatacept has shown promising results in inducing proteinuria remission, offering a successful treatment option for this challenging condition [6].

Intensive and prolonged treatment of FSGS recurrence can rapidly achieve complete and sustained remission in a significant portion of patients, with most achieving very low levels of proteinuria within 3–12 months [7]. However, the effectiveness of pretransplant prophylaxis with plasmapheresis/rituximab in preventing primary FSGS recurrence remains uncertain, suggesting the need for further research in this area [8].

Aim

We aimed to assess the prevalence, risk factors, outcome of KTRs with and without recurrent FSGS.

Patients and methods

This study was approved by the ethical committee of ministry of health of Kuwait. Out of 3221 KTRs who are actively followed up in Hamed Al-Essa Organ Transplant Center in Kuwait till the end of 2020, 109 patients with FSGS were enrolled in this observational study. They have been divided into two groups: cases with primary FSGS (n = 57) and cases with secondary FSGS (n = 52). All patients in the two groups were followed up for 12 months after transplant. We have subanalyzed the primary FSGS cases comparing those with and without recurrence and evaluated risk factors of recurrence in addition to the management plan and outcome. We have studied the demographics of two groups in addition to pretransplant and posttransplant comorbidities and finally the patient and graft outcomes.

Patients' data enrolled in our study were collected after reviewing our institution's electronic medical records. These data included clinical features, laboratory results, and associated comorbid conditions. Moreover, the transplant-related and immunosuppression-related data were smuggled from the transplant master database.

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the ethical committee of Ministry of Health of Kuwait. All data are available upon request to the corresponding author.

FSGS recurrence was defined as having proteinuria of more than 3 g/day, whatever the time of onset after transplantation. It was mandatory to eliminate other causes of early de-novo proteinuria, including acute humoral rejection (donor-specific antibodies, increased serum creatinine, decreased diuresis). Kidney graft biopsy was not systematic; that is, it was only performed when recurrence occurred late after transplantation or in the event of presence of a donor-specific alloantibody (or alloantibodies).

Complete remission was defined as having proteinuria less than 0.5 g/day for at least two consecutive weeks. Partial remission was defined as a reduction in proteinuria to 0.5–3 g/day or having decreased proteinuria of more than 50% from the baseline value for at least two consecutive weeks.

The main objective was to assess the survival of the renal transplant according to FSGS relapse, which was then treated by apheresis and/or rituximab.

Inclusion/exclusion criteria

All patients with primary kidney disease as FSGS (either primary or secondary) were included in this study and we excluded cases GN other than FSGS.

Follow up and immunosuppression protocol

According to the local follow-up protocol, all patients were followed up in Hamed Al-Essa Organ Transplant Center clinics at least every 2 months. Our immunosuppression protocol consists of five doses of antithymocyte globulin for immunologically high-risk patients (as retransplants, prior pregnancy, blood transfusion, HLA-antibody positive, and more than four HLA mismatches) or two doses of interleukin-2 receptor blocker for immunologically low-risk patients. Maintenance therapy – if no recurrence of FSGS – consisted of prednisolone, mycophenolate mofetil, and a calcineurin inhibitor. The dose of calcineurin inhibitors was gradually decreased to the lowest dose by the end of the first year, guided by a 12-h trough level. We kept the cyclosporine A level between 200 and 250 ng/ml during the first month, then between 150 and 200 ng/ml for a couple of months, then between 125 and 150 ng/ml for 2 months, and from 75 to 125 ng/ml till the end of the first year. Similarly, we kept tacrolimus trough levels between 8 and 10 ng/ml during first 3 months, then from 5 to 8 ng/ml after that. After 3 months of transplantation, maintenance immunosuppression with a sirolimus-based regimen was used among rejection-free patients with low immunological risk.

Acute cellular rejection was treated with intravenous methylprednisolone sodium succinate (methylprednisolone 1 g daily for 3 days) and or thymoglobulin (1 mg/kg for 7 days) for steroid-resistant rejection. Antibody-mediated rejection was treated with intravenous methylprednisolone sodium succinate

(methylprednisolone 1 g daily for 3 days) with one or more plasma exchanges (PE), IVIG (2 g/kg), and rituximab. Patients who received thymoglobulin as an antirejection were managed by secondary prophylaxis for 3 months for cytomegalovirus and *Pneumocystis jirovecii*. Patients were monitored daily during the hospital stay, then at each outpatient visit with serum creatinine, creatinine clearance, liver function tests, complete blood picture, drug levels, and lipid profile.

Treatment protocol of focal segmental glomerulosclerosis recurrence

Treatment of FSGS recurrence consisted of intensified PE sessions: that is, every other day for 2 weeks, and was then adapted to proteinuria level. Patients also received methyl-prednisone pulses (10 mg/kg for three consecutive days) or prednisone, which was increased at 1 mg/kg/day for 3 weeks and then slowly tapered along 8 weeks then 0.2 mg/kg/day or a maximal daily dose of 10 mg thereafter and keeping the cyclosporine (target blood level: 200–400 ng/mL) or tacrolimus (target trough level: 8-10ng/ml) at a higher level than the standard protocol. Rituximab was also given (375 mg/m^2 of body surface area) at the fourth and eighth apheresis sessions.

Apheresis

The plasma volume was treated as one plasma volume calculated using Kaplan's formula: PV = 0.065 × weight (kg)×(1 – hematocrit). The replacement fluid used was 5% albumin except in the immediate pretransplantation and posttransplantation sessions, when fresh frozen plasma was used as the replacement fluid. Patients with primary FSGS received two sessions of PE pre-transplant and another two sessions after transplant as a prophylactic measure (only for four cases). Once recurrence of FSGS was documented by biopsy we proceeded for the intensified PE sessions.

Rituximab

Rituximab was administered twice 2 weeks apart, then every 6 months depending on the clinical–biological evolution (nephrotic syndrome, serum albumin, proteinuria). When combined with apheresis, rituximab was always given after an apheresis session. The next post-rituximab apheresis session was performed 72 h after the rituximab injection to minimize drug elimination during apheresis. Of course, we have excluded cases with hepatitis B from receiving such drug.

Statistical analysis

Statistical analyses were performed using SPSS, version 26 (SPSS, Chicago, Illinois, USA). Qualitative data were presented as numbers and percentages, and quantitative data were presented as means and SD. We used the *t* test was used to compare the means and SDs of the studied groups. We compared categorical variables using the χ^2 test. *P* values were considered significant if they were less than 0.05.

Results

Most patients in the two groups (primary and secondary FSGS) were men (61.4 vs. 59.6%, $P = 0.84$) in their middle age (35.6 ± 16 vs. 44 ± 13, $P = 0.04$) years, respectively. The two groups were matched – Table 1 – regarding their demographics especially the mode of dialysis, type of donor, pretransplant comorbidities, type of induction and maintenance immunosuppression ($P > 0.05$). The majority of patients had immediate graft function without significant difference between the two groups (Table 1, $P > 0.05$). Regarding posttransplant complications (either immunological as rejection episodes or nonimmunological as BKV and CMV infections and posttransplant diabetes mellitus), we found no significant difference between the two groups (Table 2, $P > 0.05$). Moreover, graft function (as represented by serum creatinine) was comparable in the two groups at different time intervals (Table 3, $P > 0.05$). This was reflected on both the patient and graft outcomes which came parallel in the two groups (Table 2, $P > 0.05$).

Out of 57 patients, we reported 10 (17.5%) cases with recurrence. In the subanalysis of primary FSGS cases shown in Table 4, we found that the group with biopsy-proven recurrent FSGS ($n = 10$ cases) had significantly younger age ($P = 0.02$) otherwise comparable demographics in relation to the group without recurrence ($n = 47$ cases, $P > 0.05$). However, we found significant higher prevalence of patients who were sensitized against tuberculosis among cases with recurrence ($P = 0.03$).

In Table 5, we observed that more than 40% of primary FSGS were kept on angiotensin-receptor blockers or angiotensin-converting enzyme inhibitors without significant difference between the recurrent or nonrecurrent groups ($P > 0.05$). Most patients in the group with recurrent FSGS received PE (70 vs. 36.2%, $P = 0.049$) and rituximab (70 vs. 23.4%, $P = 0.004$) compared to the group without recurrence, respectively. The mean number of PE sessions was higher in the group with recurrence (11 vs. 6.3, $P = 0.38$) but did not rank to significance.

In Table 5, we observed that the basal laboratory parameters (proteinuria, plasma albumin, and serum

Table 1 The demographics of the studied population

Variables	Primary FSGS (*n*=57), *n* (%)	Secondary FSGS (*n*=52), *n* (%)	*P*
Nationality			
Kuwaiti	37	37	
Non-Kuwaiti	20	15	0.48
Sex			
Male	35 (61.4)	31 (59.6)	
Female	22 (38.6)	21 (40.4)	0.84
Mean age at transplant (years)	35.6±16	44±13	0.04
Dialysis mode			
Preemptive	14 (24.6)	12 (23.1)	
Hemodialysis	38 (66.8)	37 (71.1)	
Peritoneal dialysis	5 (8.8)	3 (5.8)	0.42
Donor type			
Living	47 (82.5)	48 (92.3)	
Deceased	10 (17.5)	4 (7.7)	0.29
Immunosuppression			
Induction			
None	8 (14)	6 (11.5)	
Basiliximab	17 (29.8)	9 (17.3)	
Lymphocyte depleting agents	23 (40.4)	22 (42.3)	
Others	9 (15.8)	15 (28.9)	0.38
Maintenance			
Cyclosporin based	27 (47.4)	22 (42.3)	0.93
Tacrolimus based	31 (52.6)	29 (55.7)	
Prophylactic PE	21 (36.8)	2 (3.8)	<0.001
Pretransplant comorbidities			
HCV infection	0 (0.0)	3 (5.8)	0.068
Hypertension	49 (85.9)	45 (86.5)	0.577
Diabetes mellitus	7 (12.3)	9 (17.3)	0.44
Ischemic heart disease	7 (12.3)	5 (9.6)	0.527
Tuberculosis (positive skin test)	20 (35)	21 (40.3)	0.491
Cytomegalovirus IgG	50 (92.6)	52 (100)	0.41
Dyslipidemia	11 (19.2)	7 (13.4)	0.44
Immediate graft function			
Immediate	40 (70.1)	29 (55.7)	
Slow	9 (15.7)	12 (23)	
DGF	4 (7)	4 (7.6)	
Unknown	4 (7)	7 (13.4)	0.159

FSGS, focal segmental glomerulosclerosis.

Table 2 Posttransplant complications in the studied patients

Variables	Primary FSGS (*n*=57), *n* (%)	Secondary FSGS (*n*=52), *n* (%)	***P***
Posttransplant complications			
BK viremia	9 (15.3)	7 (13.4)	0.646
BK nephropathy	3 (5.2)	1 (1.9)	0.337
CMV viremia	10 (17.5)	15 (28.8)	0.16
NODAT	14 (24.5)	12 (23)	0.77
Mean rejection episodes	1.71±1.68	1±1	0.22
Graft outcome			
Functioning	50 (87.7)	43 (82.7)	
Failed	7 (12.3)	9 (17.3)	0.45
Patient outcome			
Living	57 (100)	48 (92.3)	
Dead	0	2 (3.8)	
Lost follow up	0	2 (3.8)	0.06

FSGS, focal segmental glomerulosclerosis.

creatinine) were comparable in the two groups ($P > 0.05$). Follow up laboratory parameters showed significantly higher mean serum creatinine after 6 months onwards ($P < 0.05$), significantly higher proteinuria after 3 months onwards ($P < 0.05$) and significantly lower mean plasma albumin at third and

Table 3 Follow-up parameters of the studied patients

Variables	Primary FSGS (*n*=57), mean±SD	Secondary FSGS (*n*=52), mean±SD	*P*
Pretransplant weight (kg)	71.5±21	80.8±18.8	0.023
Weight at last follow up (kg)	75.4±17	86.4±23	0.021
Serum creatinine (μmol/l)			
Basal	118±53	121±49	0.78
6 months	123±64	114±35	0.43
1 year	121±77	121±72	0.98
3 years	145±147	115±46	0.26
5 years	124±61	158±195	0.42
10 years	160±113	118±22	0.24

FSGS, focal segmental glomerulosclerosis.

12th months of follow up ($P < 0.05$). However, the graft outcome was comparable in the two groups ($P > 0.05$).

Discussion

The recurrence of FSGS after renal transplantation is a well-known challenge, representing a leading cause of allograft failure in affected patients [9]. Our study provides insights into the characteristics and outcomes of patients with primary versus secondary FSGS, as well as factors associated with recurrence within a single-center cohort. The results from our local experience align with several key findings in the literature while also identifying a novel potential risk factor for recurrence. In our study, the recurrence rate was 17.5% in patients with a pretransplant primary FSGS. This prevalence came less than that reported in a multicenter trial (30%) by Uffing *et al.* [10] and Wood *et al.* [4] who reported higher recurrence rate (26%) in their retrospective analysis. Moreover, higher recurrence rates (47 and 54%) were reported by Naciri Bennani *et al.* [8] and Vallianou *et al.* [11], respectively, in their case series of primary FSGS on the kidney transplant. Our adopted immunosuppressive policy and pretransplant PE might explain the lower recurrence rate in our cohort.

In a large multicenter international registry study (TANGO) recognized 157 patients with primary FSGS who underwent kidney transplantation [10]. Fifty-seven patients had recurrent disease (about 36 vs. 17.5% in our study and 26% in Wood *et al.* [4] study). In 9/57 or 15% of cases, patients were treated empirically for recurrence based on clinical suspicion without biopsy confirmation as opposed to 0/10 (0%) in our cohort. Most of our patients had partial remission compared to 50% in TANGO study and 21% with complete remission. Our adopted immunosuppressive policy might explain the lower recurrence rate in our cohort.

Consistent with previous large-scale studies [10], our data revealed that patients with primary and secondary FSGS were comparable in most demographic and clinical aspects. Both groups exhibited a male predominance and similar mean age, and were well-matched with respect to donor type, pretransplant comorbidities, and immunosuppression regimens. This comparability underscores the validity of direct outcome comparisons between the two groups. Our findings further demonstrate that there was no significant difference in immediate graft function or the prevalence of posttransplant complications, whether immunological or nonimmunological. Importantly, our results indicate that graft function, as measured by serum creatinine, remained comparable between the primary and secondary FSGS groups at various time intervals, which was reflected in the parallel patient and graft survival outcomes. This suggests that in our cohort, secondary FSGS did not carry a significantly different prognosis compared to primary FSGS.

A focused subanalysis of patients with primary FSGS, as detailed in Table 4, sought to identify factors predisposing to disease recurrence. While the demographic characteristics of the recurrence and nonrecurrence groups were similar, a noteworthy and statistically significant finding was the higher prevalence of patients sensitized against tuberculosis in the group with biopsy-proven recurrent FSGS ($P = 0.03$). This observation is particularly intriguing and warrants further investigation, as it suggests a potential link between an underlying inflammatory or immune-sensitized state and the risk of FSGS recurrence. This is a new finding and could imply that a specific immunological profile, possibly triggered or modulated by past exposure to infectious agents, may contribute to the pathogenic process leading to recurrence.

In terms of management, our data highlights the common use of specific therapeutic interventions in the recurrent FSGS group. More than 40% of patients with primary FSGS were on angiotensin-receptor blockers or angiotensin-converting enzyme inhibitors with no significant difference between the groups. However, a significant proportion of patients with recurrent FSGS received PE (70 vs. 36.2%, $P = 0.049$) and rituximab (70 vs. 23.4%, $P = 0.004$) compared to those without recurrence. This observation was matched with that reported by Wood *et al.* [4] who adopted a similar management plan. Consecutively, we have reported partial remission in most cases but with slightly higher graft loss (20 vs. 12% in that study). The difference in the graft outcome might be due to the smaller number of patients (10 cases) in our cohort. The available data reflect the lack of standard guidelines on the treatment of recurrent FSGS.

Table 4 The demographics of the primary focal segmental glomerulosclerosis with and without recurrence

Variables	Primary FSGS [*n* (%)]		
	No recurrence (*n*=47)	Recurrent (*n*=10)	*P*
Nationality			
Kuwaiti	29 (61.7)	8 (80)	
Non-Kuwaiti	18 (38.3)	2 (20)	0.27
Sex			
Male	31 (66)	4 (40)	
Female	16 (34)	6 (60)	0.12
Mean age at transplant (years)	36.0±16.6	32.9±18.8	0.02
Donor type			
Living	38 (80.9)	9 (90)	
Deceased	9 (19.1)	1 (10)	0.24
Dialysis mode			
Preemptive	12 (25.5)	2 (20)	
HD	32 (68.3)	6 (60)	
PD	3 (6.4)	2 (20)	0.30
Immunosuppression			
Induction			
None	8 (17)	0	
Basiliximab	12 (25.5)	5 (50)	
Lymphocyte depleting agents	20 (42.5)	3 (30)	
Others	7 (14.9)	2 (20)	0.23
Maintenance			
Cyclosporin based	21 (44.6)	5 (50)	
Tacrolimus based	25 (53.1)	5 (50)	0.31
Pretransplant comorbidities			
Hypertension	40 (85.1)	9 (90)	0.216
Diabetes mellitus	5 (10.6)	2 (20)	0.410
Ischemic heart disease	5 (10.6)	2 (20)	0.410
Tuberculosis (positive skin test)	14 (29.8)	6 (60)	0.034
Cytomegalovirus IgG	41 (87.2)	9 (90)	0.410
Immediate graft function			
Immediate	36 (76.6)	8 (80)	
Slow	9 (19.1)	0	
DGF	2 (4.3)	2 (20)	0.139

FSGS, focal segmental glomerulosclerosis.

Although most centers used plasmapheresis with or without rituximab, treatment varied in both intensity and duration. So, nonstandardized treatment approach may explain the different rate of treatment response, especially regarding the achievement of complete remission [7,12,13].

The aggressive use of these therapeutic interventions in the recurrence group is consistent with established protocols for managing FSGS recurrence and reflects the clinical judgment to combat the ongoing disease process [14,15]. The mean number of PE sessions was also higher in the recurrence group, although this difference did not reach statistical significance.

Follow-up laboratory parameters provide a clearer picture of the clinical course of recurrence. The group with recurrent FSGS exhibited significantly higher mean serum creatinine after 6 months onwards ($P < 0.05$), higher proteinuria from 3 months onwards ($P < 0.05$), and lower mean plasma albumin at the third and 12th months ($P < 0.05$). These changes confirm the clinical and laboratory deterioration associated with FSGS recurrence, which is a hallmark of the disease [16].

However, despite these biochemical signs of disease, the overall graft outcome remained comparable between the recurrent and nonrecurrent groups ($P > 0.05$). This seemingly contradictory finding may be explained by the timely and aggressive treatment protocols (including PE and rituximab), which, although not leading to a complete reversal of all laboratory abnormalities, may have been sufficient to prevent significant short-term graft loss [17]. It is also possible that the limited number of cases with recurrence prevented us from detecting a significant difference in long-term graft survival.

Conclusion

Our study confirms the comparable outcomes between primary and secondary FSGS patients following renal

Table 5 Follow-up and management parameters of the primary focal segmental glomerulosclerosis with and without recurrence

Variables	Primary FSGS [*n* (%)]		
	No recurrence FSGS (*n*=47)	Recurrent FSGS (*n*=10)	*P*
Prophylactic PE	17 (36.2)	4 (40)	0.85
Prophylactic rituximab	11 (23.4)	2 (20)	0.79
FSGS treatment			
ACEi/ARB	21 (44.7)	4 (40)	0.78
PE	0	7 (70)	<0.001
Rituximab	0	7 (70)	<0.001
PE sessions (mean±SD)	6.33±2.8	11±8.03	0.38
Weight at last follow up (kg)			
Serum creatinine (μmol/l) (mean±SD)			
Basal	124±77	150±73	0.332
3 months	108±38	117±35	0.488
6 months	106±39	189±160	0.003
1 year	107±38	260±330	0.003
Last follow up	144±125	202±197	0.245
Plasma albumin (g/dl) (mean±SD)			
Basal	31±9.1	27±5.3	0.20
3 months	33±6.4	27±5.2	0.015
6 months	34±5.9	30±8.4	0.119
1 year	34±5.6	29±3.5	0.013
Last follow up	36.9±4.6	33.7±5.5	0.059
Proteinuria (g/24 h) (mean±SD)			
Basal	0.91±0.82	1.3±1	0.205
3 months	0.26±0.44	1.5±2	<0.001
6 months	0.31±0.66	1±1.22	0.019
1 year	0.37±0.71	1±1.5	0.059
Last follow up	0.79±1	1.9±1.1	0.004
Graft outcome			
Functioning	42 (89.4)	8 (80.0)	
Failed	5 (10.6)	2 (20.0)	0.41

ACEi/ARB, angiotensin-converting enzyme inhibitors/angiotensin-receptor blockers; FSGS, focal segmental glomerulosclerosis; PE, plasma exchange.

transplantation. Recurrence of primary FSGS is a serious event, occurring in about one in six patients. It is characterized by early, severe dysfunction (evident within 3 months), heavy proteinuria, and hypoalbuminemia, despite aggressive treatment with PE and rituximab. Prophylactic PE had no significant impact on the recurrence. The key novel finding is the significant association between sensitization against tuberculosis and the recurrence of primary FSGS, suggesting a potential role of a pre-existing immune-sensitized state that will need further evaluation on a larger scale. While patients with recurrence showed expected signs of disease progression, aggressive use of PE and rituximab may have contributed to a similar overall graft outcome in the short-to-medium term. Further research is warranted in a larger, multicenter cohort to validate the association with tuberculosis sensitization and to better evaluate the long-term efficacy of various therapeutic interventions for recurrent FSGS.

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Conflicts of interest

There are no conflicts of interest.

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