



Long-Term Follow-up Results of Renal Transplantation in Pediatric Patients With Focal Segmental Glomerulosclerosis: A Single-Center Experience

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ABSTRACT

Introduction and Aim. Focal segmental glomerulosclerosis (FSGS) is a common cause of end-stage renal disease in children. We analyzed the long-term outcome of pediatric patients with FSGS undergoing renal transplantation. The objective of the study is to report the experience of a single center and determine the incidence of recurrence, rejection, graft loss, and related risk factors.

Materials and Method. This retrospective cohort study was performed between 1991 and 2018. Thirty patients with a pathologic diagnosis of primary FSGS were included in the study. The patients were diagnosed with FSGS according to histologic features in biopsies.

Results. Twenty-one of the donors were deceased (70%) and 9 were alive (30%). FSGS recurred in only 2 patients. Graft loss occurred in 6 patients (20%). The causes of graft loss were chronic rejection in 4 patients and acute rejection in 2. Our graft survival rate was 100% at 1 year, 91% at 5 years, 80% at 10 years, 70% at 15 years, and 42% at 20 years. Five- and 10-year graft survival rates were 83% and 83% in living donors and 94% and 79% in deceased donors, respectively. According to Kaplan-Meier analysis, there was no statistically significant difference in terms of graft survival between living and deceased donors.

Conclusion. This study, with its contribution to literature in terms of long follow-up of FSGS patients from childhood to adulthood, is important. However, further studies are required.

NEPHROTIC syndrome, with an incidence of 2–16.9 per 100,000 children worldwide, is one of the most common glomerular diseases of childhood [1]. Focal segmental glomerulosclerosis (FSGS) manifesting as nephrotic syndrome is a clinicopathologic diagnosis characterized by segmental sclerosis in some glomeruli; the majority of such patients are resistant to steroid therapy [2]. According to the 2014 North American Pediatric Renal Transplant Cooperative Study (NAPRTCS) data, FSGS is the most prevalent acquired renal disease among transplant recipients [3].

While the rate of recurrence ranged between 20%–50%, graft loss was reported to be 30%–50% in earlier studies. High rates of recurrence and graft loss prove that there are unexplained factors in the pathogenesis of the disease [4–6]. In this study we analyzed the long-term outcome of FSGS patients undergoing renal transplantation in our center. The

objectives of the study are first to report on 27 years of experience of a single center and second to determine the incidences of recurrence, rejection, graft loss, and related risk factors.

MATERIALS AND METHODS

Patients

Between November 1991 and September 2018, 205 children (<18 years of age) underwent renal transplantation at Ege University

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Transplantation Center. These patients were evaluated retrospectively. Thirty patients with pathologic diagnosis of primary FSGS, having a follow-up at least 1 year were included in the study. Endpoints were transplant failure or the last visit. In the fourteenth and nineteenth months after transplantation, 2 patients were discharged from follow-up due to relocation. Patients' date of birth, sex, end-stage renal disease (ESRD) age, dialysis information, donor information, mismatch numbers, warm and cold ischemia times, post-transplant treatment protocols, rejection episodes, recurrence, graft loss, and survival data were recorded. Serum urea, creatinine, uric acid, total protein, albumin, urine protein, and estimated glomerular filtration rate levels were recorded after the transplantation. The updated Schwartz formula was used to calculate the estimated glomerular filtration rate levels [7].

Treatment and Follow-up Protocol

All patients underwent implantation biopsy and were evaluated using Doppler ultrasonography and diethylene triamine pentaacetic acid (DTPA) measurements on postoperative day 1. All patients also received anti-thymocyte globulin (ATG) with monitoring CD3 levels or basiliximab as an induction therapy, as well as 30 mg/kg methylprednisolone with a maximum dose of 1 g as induction therapy. Following induction, corticosteroid was tapered to 20 mg/d and continued for 6 months. In addition to prednisolone, patients received a combination of azathioprine and tacrolimus, which we named treatment protocol A, or mycophenolate sodium and a calcineurin inhibitor (tacrolimus or cyclosporine), which we named treatment protocol B. Azathioprine dosage was 1.5–2 mg/kg per day. Tacrolimus and cyclosporine dosages were 0.1–0.3 mg/kg and 3–5 mg/kg per day, respectively. Mycophenolate sodium dosage was 400 mg/m² twice daily. Subsequent dosages of calcineurin inhibitors were regulated according to drug blood levels. Following transplantation, patients were commenced on trimethoprim and sulfamethoxazole, nystatin, and acyclovir prophylaxis for 6 months against *Pneumocystis carinii* pneumonia, fungi, and viruses. Patients were followed up once a week for the first 8 weeks and then every 2 weeks for the next 4 months after transplantation.

Definitions

The patients were diagnosed with FSGS according to histologic features in biopsies. Post-transplant recurrence of FSGS was defined as the presence of hypoalbuminemia (<2.5 g/dL) and edema associated with nephrotic proteinuria and proven by biopsy findings. Nephrotic proteinuria was defined according to the criteria of the International Study for Kidney Diseases in Children as >40 mg/m² per hour or a urinary protein/creatinine ratio >2 [8]. Nephrotic syndrome patients underwent biopsy and those without histologic acute rejection characteristics were considered to be recurrences. Delayed graft function was defined as dialysis requirements within 1 week after transplantation [9].

Statistical Analysis

Continuous data were defined according to mean \pm standard deviation under parametric conditions and median (min-max) under nonparametric conditions. Categorical variables were defined by number and percentage. χ^2 analysis was used for categorical variables and the Mann-Whitney U test for continuous variables. Factors affecting acute rejection were modeled by Cox regression analysis. Survival analysis was performed using the Kaplan-Meier method, incorporating the log-rank test. The statistical significance was accepted as $P < .05$.

RESULTS

Patients and Transplantation Characteristics

Thirty patients diagnosed with FSGS included in the study. This represents 14.6% of the total number of pediatric patients who underwent renal transplantation with ESRD. Thirteen of the patients were male while 17 were female. The median age of the patients at the time of transplantation was 11.2 years and the median follow-up period was 8.5 years. The median ESRD age of the patients was 8.3 years and the median duration of pre-transplant dialysis was 14 months. Before transplantation, 13 patients were on the hemodialysis program and 14 were on peritoneal dialysis; 3 were transplanted preemptively. Twenty-one of the donors were deceased (70%) and 9 were alive (30%). The median age of the donors was 30.5 years. The median warm ischemia time was 23.5 minutes and the median cold ischemia time was 8.4 hours. Patients' characteristics are shown in Table 1. Before transplantation, 13 (43.3%) of the patients were oliguric and 23 (76.7%) were hypertensive. There was no statistically significant difference in terms of hypertension in patients who were oliguric or non-oliguric ($P = .104$).

Treatment Protocols

ATG was used as induction therapy in 24 patients (80%) and basiliximab in 6 (20%). As maintenance therapy, 10 (33.3%) patients were commenced on protocol A and 20 (66.7%) on protocol B. The relationship between induction therapy and maintenance protocols with acute rejection were examined, but no statistically significant relationship was found between treatment protocols and rejection ($P = 1.000$, $P = 1.000$). One other patient underwent 3 sessions of plasmapheresis and intravenous immunoglobulin (IVIG) treatments before transplantation. This case was diagnosed as familial FSGS and a renal transplantation from the patient's father was planned for the year 2006. In past years, plasmapheresis and IVIG treatments were administered before a transplantation

Table 1. Patient Characteristics

| Patient Characteristics | (N = 30) |
|---|----------------|
| Sex (male/female) | 13/17 |
| Dialysis modality (HD/PD/preemptive) | 13/14/3 |
| Donor type (deceased/living) | 21/9 |
| Relation of living donors (mother/father/grandfather) | 6/2/1 |
| Rejection (acute/chronic) | 6/3 |
| FSGS recurrence | 2/30 |
| Graft loss | 6/30 |
| | Median (Range) |
| Age at ESRD (y) | 8.3 (1–18) |
| Time on dialysis prior to transplantation (mo) | 14 (2–84) |
| Age at transplantation (y) | 11.2 (2–18) |
| Donor age (y) | 30.5 (1–65) |
| Warm ischemia time (min) | 23.5 (1–45) |
| Cold ischemia time (min) | 504 (15–1800) |
| Follow-up period (y) | 8.5 (1.5–20) |

Abbreviations: ESRD, end-stage renal disease; FSGS, focal segmental glomerulosclerosis; HD, hemodialysis; PD, peritoneal dialysis.

to a recipient from a living related donors. FSGS recurrence did not occur in this patient.

Graft Function

DTPA scans of 16 patients were consistent with acute tubular necrosis (ATN), while 14 patients' results were normal. Only 2 patients needed dialysis session in the first week after transplantation and were accepted as delayed graft function. Deceased donors accounted for 81.3% of the ATN group and 64.3% of the normal group. Both groups were similar in terms of donor type, warm and cold ischemia times, and time to reach basal creatinine, respectively ($P = .417$, $P = .462$, $P = .082$, $P = .790$). However, the mean donor age was 41.7 ± 16.2 years in the normal group and 20 ± 15.1 years in the ATN group, which was statistically significant ($P = .001$). There was no statistically significant relationship between the presence of ATN in DTPA with acute rejection and graft loss ($P = 1.000$, $P = .378$).

Recurrence

FSGS was only recurred in 2 patients. The characteristics of these patients are presented in Table 2. The recurrent patient 1 received 16 sessions of plasmapheresis, 2 doses of IVIG, and 2 doses of rituximab. The second patient received 3 sessions of plasmapheresis and 3 pulses of methylprednisolone (30 mg/kg per day). Both responded clinically to the treatments and their grafts are still functioning well. Laboratory values and final statuses of both cases before and after recurrence are shown in Table 3.

Rejection and Graft Survival

Rejection. Six of the patients (20%) had acute rejection episodes during their follow-up, while 3 (10%) were diagnosed as chronic rejection. Patients with acute rejection were similar in terms of age, sex, donor type, and donor sex and age, respectively. Their characteristics are presented in Table 4. When the patients were grouped in terms of induction therapy and treatment protocol, there was no

Table 2. Characteristics of the Cases With Recurrent FSGS

| | Recurrent Patient 1 | Recurrent Patient 2 |
|---|---------------------|---------------------|
| Age at time of diagnosis (y) | 8 | 4 |
| Age at ESRD (y) | 14 | 8 |
| Sex | F | M |
| Dialysis (mo) | PD (9) | PD (84) |
| Donor | Deceased | Deceased |
| Blood type | B to B | B to B |
| HLA mismatch | 5 mm | 3 mm |
| Age at transplant (y) | 15.5 | 15 |
| Recurrence (time after transplantation) | 6.5 years | Day 26 |
| Induction therapy | Basiliximab | ATG |
| Maintenance therapy | Tacrolimus + AZA | Tacrolimus + MMF |

Abbreviations: AZA, azathioprine; ATG, anti-thymocyte globulin; ESRD, end-stage renal disease; FSGS, focal segmental glomerulosclerosis; MMF, mycophenolate mofetil; PD, peritoneal dialysis.

Table 3. Recurrence and Clinical Follow-up

| | Recurrent Patient 1 | Recurrent Patient 2 |
|---------------------------------------|------------------------------|-------------------------------|
| Date of transplantation | July 20, 2006 | November 14, 2012 |
| Date of recurrence | March 26, 2013 (Year 6.5) | December 10, 2016 (Day 26) |
| Proteinuria before recurrence | 2* | 6 [†] |
| Proteinuria at the time of recurrence | 124* | 7.5 [†] |
| Proteinuria after treatment | 3* | 1 [†] |
| Postoperative day 1 proteinuria | 103* | 8.8 [†] |
| Postoperative day 7 proteinuria | 89* | 6.8 [†] |
| Postoperative day 30 proteinuria | 7* | 6 [†] |
| Postoperative year 1 proteinuria | 2* | 0.3 [†] |
| Postoperative year 5 proteinuria | 1.6* | 0.2 [†] |
| Last follow-up (y) | 12 | 6 |
| Proteinuria at last follow-up | 1* | 0.15 [†] |
| eGFR at last follow-up | 90 mL/dk | 75 mL/dk |

Abbreviation: eGFR, estimated glomerular filtration rate.

*mg/m² per hour in collected urine.

[†]Urine pr/cr ratio.

statistically significant relationship between acute rejection and treatments ($P = 1.000$, $P = 1.000$). There was no statistically significant relationship between acute rejection and warm ischemia time or cold ischemia time and cumulative ATG doses ($P = .278$, $P = .460$, $P = .969$). In the Cox regression analysis, when mismatch, warm and cold ischemia times, donor age and sex, ESRD age, and duration of dialysis were taken as factors, none had a statistically significant effect on acute rejection ($P > .05$).

Graft Survival

Graft loss occurred in 6 patients (20%). The causes of graft loss were chronic rejection in 4 patients and acute rejection in 2. Rejection, graft loss, and survival characteristics are presented in Table 5. A Cox regression analysis was performed with the factors affecting graft survival: donor and patient's age, donor sex, warm and cold ischemia times, and acute rejection were taken as factors. None of the factors were statistically associated with graft survival ($P < .05$). In our study, the mean estimated graft survival time was 117 months in living donor transplantations and 182 months in deceased donors. Our graft survival rate was 100% at 1 year, 91% at 5 years, 80% at 10 years, and 70% at 15 years, and 42% at 20 years (Fig 1).

In our study, 5- and 10-year graft survival rates were 83% and 83% in living donors and 94% and 79% in deceased donors, respectively. According to Kaplan-Meier analysis, there was no statistically significant difference in terms of graft survival between living and deceased donors (Fig 2).

Table 4. Comparison of the Characteristics of Cases According to the Status of Acute Rejection

| Categorical Variables | Acute Rejection (+) (n = 6) | | Acute Rejection (-) (n = 24) | | P* |
|--|--------------------------------|-----------|---------------------------------|-----------|-------|
| | n/n | %/% | n/n | %/% | |
| Sex (male/female) | 3/3 | 50.0/50.0 | 10/14 | 41.7/58.3 | 1.000 |
| Donor type (deceased/living) | 3/3 | 50.0/50.0 | 18/6 | 75.0/25.0 | .329 |
| Donor sex (male/female) | 3/3 | 50.0/50.0 | 15/9 | 62.5/37.5 | 1.000 |
| Pre-transplantation hypertension (hypertensive/normotensive) | 5/1 | 83.3/16.7 | 18/6 | 75.0/25.0 | 1.000 |
| Induction (ATG/basiliximab) | 5/1 | 83.3/16.7 | 19/5 | 79.2/20.8 | 1.000 |
| Treatment protocol (A/B) | 2/4 | 33.3/66.7 | 8/16 | 33.3/66.7 | 1.000 |
| Post-op dialysis need (+/-) | 1/5 | 20.0/80.0 | 1/23 | 4.2/95.8 | .377 |
| Continuous Variables | Median | (Min-Max) | Median | (Min-Max) | P* |
| Age at ESRD (y) | 11.0 | (1-18) | 7.2 | (1-16) | .980 |
| Age at transplantation (y) | 11.8 | (2-18) | 10.5 | (2-18) | .940 |
| Donor age (y) | 39 | (3-43) | 31 | (10-65) | .893 |
| Time on dialysis (mo) | 18.0 | (2-28) | 12.0 | (2-84) | .569 |
| Warm ischemia time (min) | 10 | (1-30) | 21 | (1-45) | .278 |
| Cold ischemia time (min) | 420 | (30-720) | 528 | (15-1800) | .460 |
| Cumulative ATG dosage (mg/kg) | 5.8 | (4-13) | 8.0 | (1-12) | .969 |
| Follow-up period (y) | 12.0 | (6-16) | 6.0 | (1.5-20) | .129 |

Abbreviations: ATG, anti-thymocyte globulin; ESRD, end-stage renal disease.
*P < .05.

DISCUSSION

FSGS continues to be the third most common and the most prevalent acquired renal disease according to 2014 data, with a prevalence of 11.7%. This rate was 7.7% in a 2001 report. This frequency differs in the black and white populations. The frequency of FSGS in black patients is 22.6% and it is the most common primary diagnosis among transplant recipients. Among white patients it has a prevalence of 9.0% and is still the third most common diagnosis [3]. This study showed the prevalence of FSGS as 14.6% among transplant recipients. Although our study group consisted entirely of white patients, because of the average prevalence among this population, we have a higher prevalence of FSGS than is reflected in the literature.

Recurrence of primary FSGS disease in the pediatric population, especially when single-center studies are also considered, varies from 5%–60% [4,5,10–12]. This wide range may be due to the definition of recurrence or the patient population in the centers. Different recurrence rates of different races have been reported previously. Black

patients show a lower incidence of recurrence compared to other races/ethnicities [13–15]. We observed a low recurrence rate of 6.6% in this study, which is lower than those of previous reports, although our patients all happened to be white. This lower rate may be due to the fact that we depended on biopsy findings to define recurrence, or a reflection of being a single center. The reported risk of recurrence was high as 80% in the second grafts [16]. The fact that we did not include patients with a second transplant may be the cause of this lower recurrence rate. The close relationship between FSGS recurrence and graft survival has been well established; however, there is no consensus on risk factors for recurrence in the literature. Diagnosis at a young age (particularly < 6 years), rapid progression from diagnosis to ESRD, and young transplant age have been reported as risk factors for recurrence [15,17]. We had only 2 patients with recurrence, who were 8 and 4 years old at the time of diagnosis and whose progression to ESRD lasted 4 and 6 years, respectively; at the time of transplantation both were nearly 15 years old. The

Table 5. Summary of Rejection, Graft Loss, and Survival

| | Transplant Date | AR | CR | Graft Loss (mo) | Cause of Graft Loss | eGFR at Last Visit (mL/dk) | Patient Survival (A/D) |
|------------|-------------------|----|----|-----------------|---------------------|----------------------------|------------------------|
| Patient 1 | May 26, 2002 | | + | + (156) | CR | <10 | A |
| Patient 4 | February 5, 2003 | | + | + (78) | CR | <10 | A |
| Patient 6 | February 13, 2005 | + | | | | 45 | A |
| Patient 8 | June 3, 2002 | | + | + (60) | CR | <10 | A |
| Patient 9 | November 1, 1991 | + | | + (192) | AR | <10 | A |
| Patient 13 | December 21, 2010 | + | | | | 51 | A |
| Patient 15 | May 17, 2003 | + | | | | 74 | A |
| Patient 16 | April 13, 2012 | | + | + (38) | CR | <10 | A |
| Patient 17 | June 25, 2007 | + | | | | 41 | A |
| Patient 22 | July 10, 2012 | + | | + (24) | AR | <10 | A |

Abbreviations: A, alive; AR, acute rejection; CR, chronic rejection; D, dead; eGFR, estimated glomerular filtration rate.

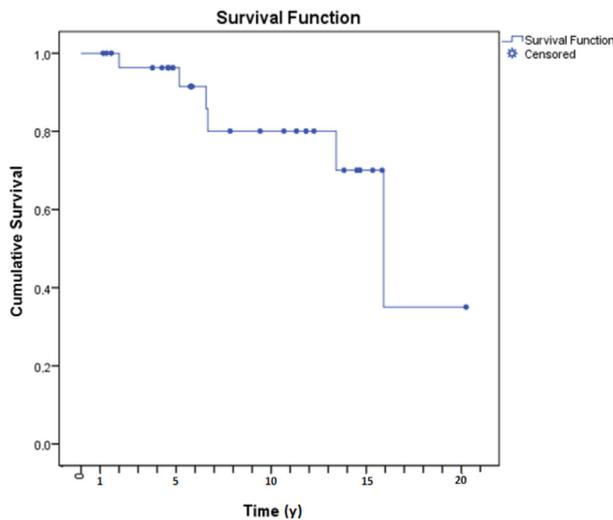


Fig 1. Kaplan-Meier analysis of overall graft survival rates of FSGS patients.

characteristics and the clinical course of these 2 patients with recurrence are shown in Tables 2 and 3. According to the analysis of data compiled by the United Network for Organ Sharing, donor type does not impact recurrence [15]. These 2 patients with recurrence had deceased donors, but this finding was considered uninterpretable because of our low recurrence rate. The effect of induction therapy on recurrence risk is also still a controversial topic. Induction therapies have been associated with either higher [18] or lower [6,19] recurrence rates in different studies. Our patients received induction therapy because this was the current protocol and these patients recurred, having been administered basiliximab and ATG induction, respectively. As a result, risk factors affecting recurrence in FSGS still

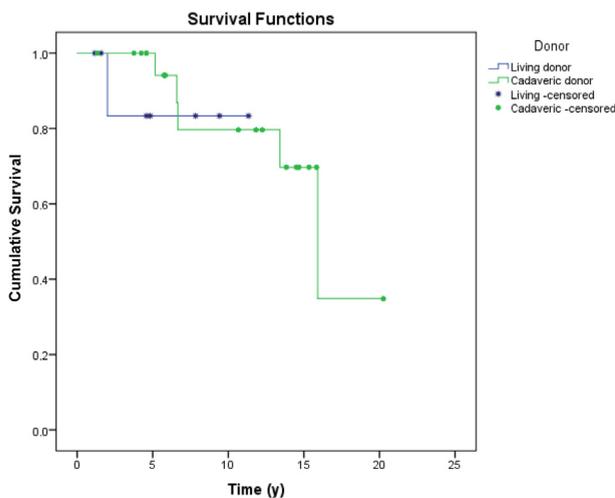


Fig 2. Survival graphics of FSGS patients with living and deceased (cadaveric) donors.

requires more evidence. The genetic and immunologic factors that play a role in recurrence also need to be clarified.

NAPRTCS data reported an acute rejection rate of 70% between the years 1987–1991 and tapered to 16% between 2007–2013. These data suggest that the most important affective factor involved in this reduction is the newly developed maintenance immunosuppressive therapies [3]. In this study group we found an acute rejection rate of 20% between the years 1991 and 2018. We observed that 86% of our FSGS patients were transplanted between the years 2002–2014, and the overall acute rejection rate was no different than the ratio reported by NAPRTCS for the same years (20.5%). This study did not show a significant relationship between acute rejection and different induction or maintenance immunosuppressive treatments. This may be the consequence of calcineurin inhibitors being administered to all patients in this group. Longer pre-transplant dialysis duration, HLA mismatch, and high pre-transplant panel-reactive antibody levels are reported as risk factors for acute rejection [20,21]. According to Cox regression analysis, variables such as HLA mismatch, warm and cold ischemia times, donor age and sex, age at ESRD, and duration of dialysis affecting rejection were also not significant.

Previous studies have reported a tendency not to use living related donors in patients with FSGS [4,6,22]. In the 2014 NAPRTCS data, patients with FSGS were reported to have a 5-year graft survival rate of 71% with living donors, and 63–67% with deceased donors [3]. Baum et al, who used NAPRTCS data from 1987–2000, noted that 5-year graft survival rate was significantly lower in FSGS with living donor patients (69%) than those with non-FSGS living donor patients (82%); on the other hand, they also reported finding no significant difference between the survival rates of FSGS living and deceased donor patients (69% and 60%) and non-FSGS deceased donor patients (67%) [22]. In addition, graft loss in recurrent FSGS patients was found to be higher in living donor transplants [3]. The advantage of living donors has been reported to be lost in patients with FSGS due to the high risk of recurrence and its effects on graft survival in analyses of NAPRTCS data [21]. On the other hand, Akioka et al, due to having difficulties in finding deceased donors, reported a series of FSGS patients who were all transplanted from living donors, with survival rates at 5 and 10 years of 79.6% and 68.2%, respectively [12]. In this study, overall graft survival rates of FSGS were 100% at 1 year, 91% at 5 years, 80% at 10 years, 70% at 15 years, and 42% at 20 years (Fig 1). The graft survival rates at 5 and 10 years were found to be 83% and 83% with living donors and 94% and 79% with deceased donors, respectively. According to Kaplan-Meier analysis, there was no statistically significant difference in terms of graft survival rates between living and deceased donors (Fig 2). The results of this study also showed a loss of living donor advantage in transplanted FSGS patients, with acceptable outcomes in both living and deceased donors, compatible with the studies cited above.

Although the advantage of having a living donor is lost in FSGS, there is no strong evidence indicating the necessity to

avoid living related donor transplantation. This study, with its contribution to literature in terms of long follow-up of FSGS patients from childhood to adulthood, is important. However, further studies are required to collect additional data on long-term follow-up results of transplanted children with FSGS.

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