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Report of the ASFA Apheresis Registry Study on Focal Segmental Glomerulo-Sclerosis

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None of the Authors have any Conflicts of Interest or financial interests related to this manuscript.

We did not receive any funding related to this manuscript.

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This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1002/jca.70041

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Abstract

Introduction: Focal segmental glomerulo-sclerosis (FSGS) is one of the causes of end-stage kidney disease. The etiology is not fully understood and standardized treatments are not established. We created a registry on apheresis for post-transplant FSGS through the Renal Subcommittee in Research Committee in American Society for Apheresis (ASFA) and here is our first report.

Study design: Members of renal subcommittee from seven centers in the United States contributed data collection on demographic, the clinical course, and overall outcomes of patients with post-transplant recurrence of FSGS treated with therapeutic plasma exchange (TPE) between 2015 and 2020. The TPE data including frequency and replacement fluid for TPE are also investigated.

Results: The median age at diagnosis of FSGS and first transplantation among 26 patients were 12.7 and 21 years, respectively. The FSGS recurred at a median 1 day after transplantation, and TPE was performed daily or every other day in the first month and continued at some frequency beyond a year in some cases. Most procedures used albumin as a replacement fluid and citrate anticoagulation, with 1-1.5 plasma volumes-exchange. Twelve patients had complete/partial remission by 6 months. The median urine protein/creatinine ratio improved from 4.47 to 1.4 mg/mg within 3 months and eGFR improved from 26 to 78 ml/min/1.73m^2 in a year after TPE started.

Conclusion: The study revealed some uniformity in prescription of TPE, primarily using albumin as replacement fluid and performing 1-1.5 plasma volume exchanges. Observed complication rates were minimal. TPE can be one of the treatments to consider in this condition.

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Introduction

Focal segmental glomerulosclerosis (FSGS) is one of the important causes of end-stage kidney disease (ESKD) in both adults and children [1]. Primary FSGS occurs when there are segmental lesions on light microscopy of the kidney biopsy along with diffuse effacement of foot processes on electron microscopy and the patient displays clinical nephrotic syndrome without antecedent injury. FSGS may also be secondary to a prior infection, to medications such as interferon or sirolimus, or due to a genetic mutation. Recurrence of FSGS after kidney transplantation can cause substantial graft loss as early as a few hours after the transplantation[2, 3] . Many circulating factors have been discussed as possible causes of FSGS recurrence, but none of them has clearly proven to be the cause. Therapeutic apheresis (TA) is used to address this putative circulating factor in patients who had post-transplant recurrence of FSGS. However, the use of TA in this setting, either in the form of therapeutic plasma exchange (TPE) or adsorption plasmapheresis, has not been studied in randomized clinical trials.

Though the post-transplant glomerular disease study (TANGO) has important details regarding recurrence of FSGS using a standardized approach for data collection [4], there is very little detail on use of TA in recurrence. Our current study, conducted through the Research Committee of the American Society for Apheresis (ASFA), has collected data regarding details of TA for treatment of FSGS recurrence after kidney transplantation.

Material and methods

Study design

The ASFA Apheresis Registry is a multi-institutional database that collects data of apheresis applications on rare-diseases or rare apheresis applications of common diseases, organized by the ASFA research

committee. Seven participating sites contributed to collect data for this FSGS registry. These facilities had obtained their Institutional Review Board (IRB) approval and a Data Usage Agreement to enter detailed de-identified patients' data retrospectively including demographic and clinical information, apheresis procedural information, treatment schedules, treatment outcomes and procedural complications. Since this was a retrospective data collection, informed consent was waived. As the study did not involve a clinical trial, it was not registered in clinical trial registration website. Study data were collected and managed using REDCap electronic data capture tools hosted at Children's National Hospital. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources [5] .

All patients received TPE as their TA modality for treatment of for the treatment of FSGS recurrence. The demographic data collected included gender, race, age at diagnosis, and age at first TPE. The TPE procedural data collected included total number of TPE, plasma volume exchanged, type of replacement fluid, type of anticoagulant, type of access, and adverse events.

Clinical data included details of native nephrectomy, details of the need for dialysis before kidney transplant and type of kidney transplant (deceased donor or living donor). Recurrence of FSGS was determined by recurrence of proteinuria after kidney transplantation (either by urine protein creatinine ratio> 2 mg/mg on a random urine specimen or by 24-hour urine protein greater than 3000 mg or edema on clinical exam or low serum albumin below 3 gm/dL or transplanted kidney biopsy showing FSGS or complete effacement of foot process. Details regarding time of recurrence of FSGS after kidney transplant and immunosuppressive therapy in addition to TPE were also collected. Outcomes recorded

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included urine protein/creatinine ratio, serum creatinine and serum albumin, at 1 month, 3 months and 1 year after TPE, whenever available.

Our primary objective was to determine practice patterns regarding use of TPE for recurrence of FSGS after kidney transplantation. Clinical outcomes after kidney transplantation with the use of TPE for FSGS recurrence were also collected as a secondary outcome.

We included both children and adults who received a kidney transplantation between 2015 and 2020, with the current study focusing on the use of TPE after recurrence in a kidney transplantation.

Statistical analysis

Data are shown as frequencies (percentages for categorical variables and as medians (IQR) or means ± standard deviation for continuous variables). We assessed kidney function by means of eGFR (CKD Epi without race for adults [6] and bedside CKiD Schwartz for children [7]. We defined remission of FSGS as urine protein to creatinine ratio less than 0.2 mg/mg and partial remission as urine protein to creatinine ratio less than 1 mg/mg [4]. Change in kidney function and urine protein to creatinine ratio at the time of recurrence and after treatment with TPE were performed by Wilcoxson matched pairs, while proportion of responses were analyzed by McNemar's Chi square or exact test.

Results

Demographics

A total of 26 patients from seven centers received TPE for recurrence of FSGS and demographics are shown in Table 1. Median age at diagnosis was 12.7 years, median age at transplantation was 21 years and 68% were male (Table 1). Prior to transplant, 85% of patients received dialysis and nearly half the patients (48%) had native nephrectomy prior to transplantation. Half of the patients (50%) received

deceased-donor transplantations, and the other half received living-donor related transplantations. FSGS recurrences occurred at a median of 1 day after the transplantation. Diagnosis of recurrence was made by elevated urine proteinuria in most patients (84.6%), and or by biopsy in 4 patients, and the data in 2 patients were not entered.

Details of TPE procedures

Three patients out of 26 patients (13%) also received pretransplant TPE. All TPE procedures used ACD-A for regional anticoagulation. . Five patients started TPE the day of recurrence, while others started within 3 days of recurrence. Two treatment centers have TPE protocol for FSGS recurrence and followed this protocol. A majority of patients (24/26) received either daily or every other day TPE when first diagnosed with recurrence. This schedule was continued for a median of 7 treatments (range, 6-12). In the initial 2 weeks of therapy replacement fluid was 5% albumin (n=16), plasma alone (n=1) or a combination of 5% albumin and plasma (n=9). TPE were either 1 plasma volume or 1-1.5 plasma volume exchanges. Three patients received tandem hemodialysis in addition to TPE. After the first 2 weeks, nearly all TPE treatments were with 5% albumin. Patients received a median of 26 treatments (range, 10-124). TPE therapy plans were primarily prescribed by transfusion medicine physicians (18) followed by nephrologists (6). More details of treatments are available in table 2

Most patients were on calcineurin inhibitors and mycophenolate for immunosuppression after kidney transplantation. In addition, patients received rituximab (n=10), steroids (n=25), and abatacept (n=1) as treatment for recurrence. See Table 4 for procedural details.

Complications

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Most patients tolerated TPE well. There were two instances of allergic reaction with plasma replacement, two instances of suspected of transfusion reactions, and three instances of asymptomatic hypocalcemia in the first 4 weeks of treatment. No procedures were aborted due to adverse events. After the first 4 weeks there were 2 instances of catheter removal and replacement (one for catheter malfunction and another for infection); the central line infection rate per 1000 central line days was 0.29. Other reactions are listed in Table 3.

Response to treatment

Lab results and outcomes

All patients but one (25/26, 96.2%) had at least 3 months of follow up data for urine protein/creatinine ratio, while 20/26 patients had at least 6 months follow up after recurrence. The majority of the patients (23/26, 88.5%) had eGFR at 6 months and 20/26 patients (73.1%) had eGFR at 1 year. One patient died about 2 years after transplant due to non-adherence to recommended treatments related to psychosocial difficulties. Median urine protein to creatinine ratio improved from 4.47 mg/mg at the start of TPE to 1.4 mg/mg 3 months after recurrence (p=0.03). By 6 months follow up after recurrence, 12 patients had reached complete or partial remission while 8 patients did not. Median eGFR was increased from 26 mL/min/1.73m^2 at the start of TPE to 78 mL/min/1.73m^2 (p=0.04) one year after the start (Tables 5a and 5b). On annual follow up after recurrence, 4 patients had progressed to ESRD needing dialysis, 7 patients had CKD (eGFR < 60 ml) while 9 patients had no CKD (EGFR > 60 ml). Median serum albumin level also increased from 2.6 gm/dL (IQR 2.4,2.9) at the time of recurrence to 4 gm/dL (IQR 3.4,4.2) at 3 months (p=0.003). See Figure 1a and 1b for temporal trends and Table 5 for ultimate patient outcomes.

Two patients had preoperative pheresis for desensitization protocol while 1 patient was for prevention of FSGS recurrence. The median proteinuria after recurrence though less in patients who had

preoperative pheresis was not statistically significant. (Median 2.01 mg/mg(IQR2,2.82) vs 10.5 mg/mg(IQR 3,20), p=0.12).

Twenty five out of 26 patients had oral steroids while 8 of the 26 patients had rituximab. Treatments details regarding dosages were available only for 6 patients. High dose solumedrol were started (2 mg/kg) on the day of recurrence and was weaned to 0.1 mg/kg by 3 month of recurrence. Rituximab at a dose of 375 mg/m^2 was given within 10 days of recurrence for these 5/6 patients. There is no difference in urine protein creatinine ratio at 6 months and eGFR at 1 year with patients who received rituximab versus those who did not (0.95 vs. 1.2 mg/mg p=0.87, 79 vs 63 ml/min/1.73m^2, p=0.58).

Six patient had late recurrence of FSGS (recurrence 45 days after kidney transplant which was the median time as per TANGO study). 4 had biopsies in addition to elevated urine protein/creatine ratio. There was no difference in urine protein creatinine ratio at 6 months (1.4 (IQR 0.23,5.9) vs 1.1 (IQR 0.64,5.7), p=0.92) or eGFR at 1 year (55 (IQR 50,75) vs 58 (IQR 20,76)) in patients who had late recurrence.

There was lower proteinuria in living donor transplants at the time of recurrence (up/cr 1.5 mg/mg vs. 8.2 mg/mg, ==0.08), which continued at 6 months (0.273 mg/mg (IQR 0.17,1.4)vs 1.4 mg/mg (IQR 0.9,10), p=0.04); however there was no difference in eGFR at a year after recurrence (60 ml/min(IQR 30,75) vs 57.9 ml/min(IQR 50,75), p=0.7)

Discussion

Focal segmental globular sclerosis is a devastating disease recurrence is reported in 30 to 60% of cases after transplantation ([2-4, 8]). Variable recurrence rates are due to inclusion of genetic or secondary causes of FSGS in pretransplantation cohorts. Recent studies have shown presence of of anti -nephrin antibody both in native nephrotic syndrome and posttransplantation recurrence of FSGS([9-11]).

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Though many studies have shown the benefit of plasma pheresis or LDL apheresis sessions in treatment of recurrent FSGS, though there are no head to head comparisons between these modalities.

Current study focuses on practice patterns and the use of TA for recurrent FSGS after kidney transplantation. Though adsorption plasmapheresis also has been used for treatment of this condition [12], none of the contributing centers submitted data on patients receiving modalities other than TPE for treatment of FSGS recurrence. Though a large number of cohort studies and case series have shown TPE as an adjunct for treatment of recurrent FSGS [13-15],our study has given detailed information about technical aspects of TPE in addition to the patients' response to TPE in short and long term.

Our study included both adults and children. The median age at diagnosis of nephrotic syndrome was 12.7 years while the median age of transplant was 21 years, this may represent a longer wait time for people diagnosed with FSGS. Though white race has been reported [4] as a risk factor for FSGS, our study had 12 (46%) patients who self-identified as black or Hispanic. Interestingly nearly, 40% of patients had a biopsy diagnosis of minimal-change disease, demonstrating the difficulty of separating between FSGS and minimal-change by biopsy alone. The majority of patients (90%) received dialysis prior to transplantation with approximately 2/3 (70%) receiving hemodialysis prior to transplantation. Native nephrectomy has been recognized as a risk factor for recurrence[4] and nearly half of our patients had native nephrectomy prior to transplantation.

Some studies have shown that use of apheresis pretransplant can prevent recurrence([14, 16]). However since FSGS is a histological diagnosis and the cohort includes monogenic and secondary causes which do not anyway recur after transplant, it is difficult to draw conclusions. Three of our patients had pretransplant TPE, however there was no difference in response rate between these patients and the rest.

We have shown that across United States, TPE with regional citrate anticoagulation is commonly used to treat FSGS recurrence. The transfusion medicine service was the most common specialty prescribing

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apheresis followed by nephrology. Most centers used albumin as replacement fluid with either 1 or 1-1.5 times plasma volume as exchange volume. Most treatments were performed daily or every other day initially and then weaned to twice a week or once a week treatments after the first 4 weeks. Though Choosing Wisely guidelines from ASFA [17] would suggest use of peripheral veins as preferred access, most patients had a central venous catheter as access (59%), while 35% of patients had an AV fistula as access for performing TPE. This may be because these patients having chronic kidney disease do not have accessible veins. Three patients also received tandem hemodialysis in addition to TPE. Similar to published studies in the literature, most patients required many treatments (median of 26 treatments in our study) to see treatment effect. Most patients received augmented immunosuppressive therapy for treatment of recurrence in addition to TPE namely steroids and rituximab. Rituximab, and anti-CD20 antibody, has been shown as an adjuvant therapy to induce remission in posttransplant FSGS ([14, 18]). The TANGO study had shown plasmapheresis with or without rituximab was associated with remission[4]. We could not see a difference with the response rate in patients who received rituximab in addition to plasmapheresis in our study. However only 8 patients in our study were noted to have received rituximab, while 3 patients did not have any data entered which makes derivation of firm conclusions difficult.

Most patients tolerated TPE well with fewer than 2% of patients having allergic reactions or suspected transfusion reactions and about 2% of patient having only biochemical hypocalcemia from citrate toxicity. Though most patients required catheters, thrombosis or infection rate was less than 0.5% of all the procedures performed. CLABSI rate of 0.29/1000 catheter days is below the reported rates of CLABSI (0.4-6/1000 catheter days) in chronic dialysis patients [19, 20]

More importantly, TPE in addition to the immunosuppressive therapy seems to be effective in reducing proteinuria with median urine protein/creatinine ratio improving from 3.05 to 1.43 (mg/mg) 3 months after the initiation of TPE treatment. Median serum albumin also increased during the same period

from 2.6 to 4 gm/dL. Median GFR also significantly increased from 26 ml/min 1/73m^2 to 76 ml/min/1.73m^2 a year after the start of TPE treatment. Complete or partial remission of FSGS was significantly associated with good graft function at 1 year (those who did not obtain remission all progressed to ESRD (4/4) while 8/9 pts who had complete or partial remission had no CKD, P=0.012, EXACT TEST), which is similar to other studies [4].

Being a retrospective study with no control group limits our ability to draw firm conclusions about efficacy of TPE. Moreover, the retrospective nature of the study led to some missing data accrual, and our outcomes were limited to 1 year. Moreover the heterogeneity of the cohort including early and late recurrences makes it harder to define outcomes. Though our registry was open to obtaining data about adsorption apheresis, none of the centers contributed data using alternative modalities. As such, it is an area of future investigation in our registry.

Conclusion

We described the practice patterns of TPE treatments for post-transplant recurrence of FSGS across centers in the United States. The study revealed some uniformity in prescription of TPE, primarily using albumin as replacement fluid and performing 1-1.5 plasma volume exchanges. Observed complication rates were minimal. TPE treatments along with immunosuppression resulted in 60% remission by 6 months. One year graft survival was 80% in this population. However only 45% patients had eGFR > 60 ml/min/1.73m^2 at 1 year signifying that more treatment options are needed to improve FSGS recurrences after kidney transplantation. This is our first report from ASFA FSGS registry and the number of our patients in this study is still small. We will continue working on collecting the data with all apheresis modalities.

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Figure 1a:

Legend : Proteinuria as measured by urine protein/creatinine ratio (mg/mg) from a week after starting apheresis to 6 months after starting apheresis, showing response at 3 months but not sustained completely at 6 months

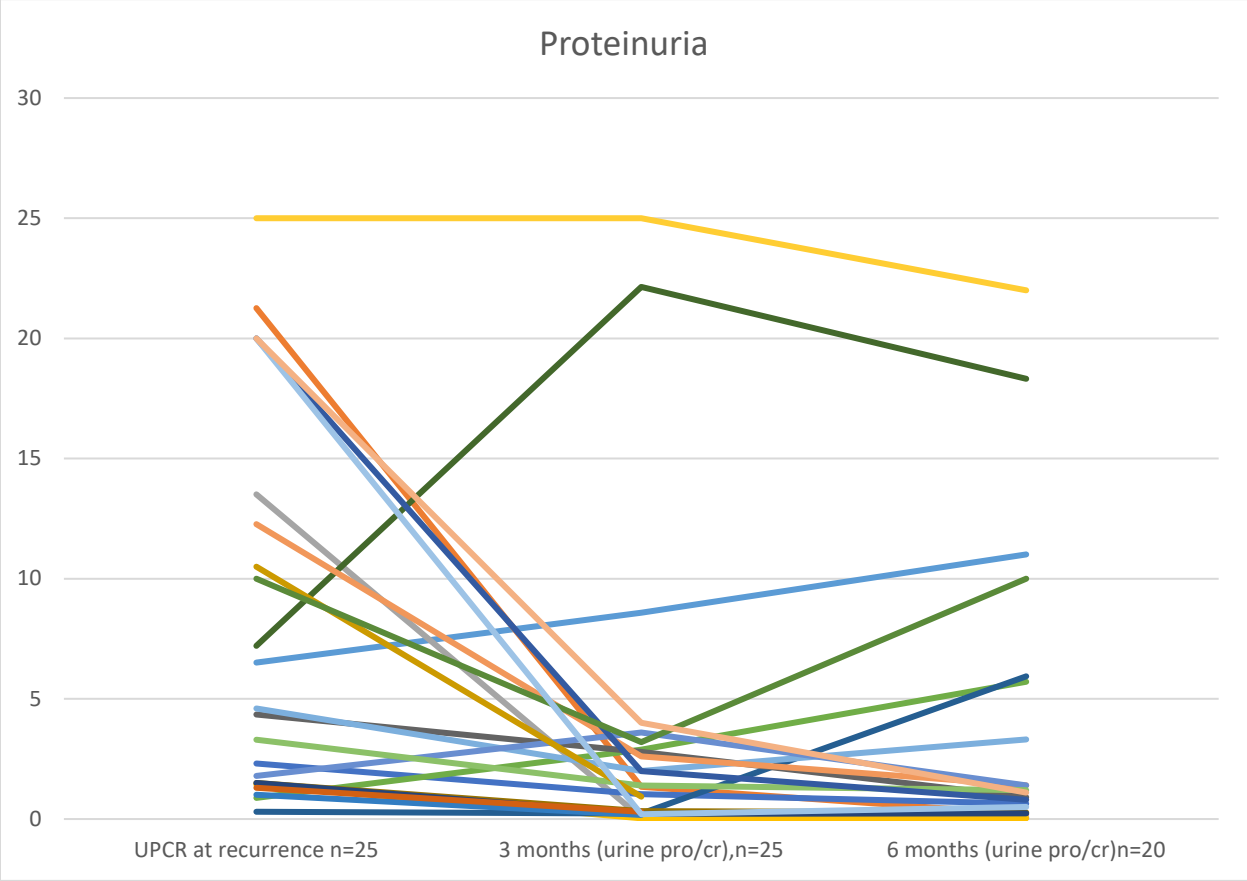
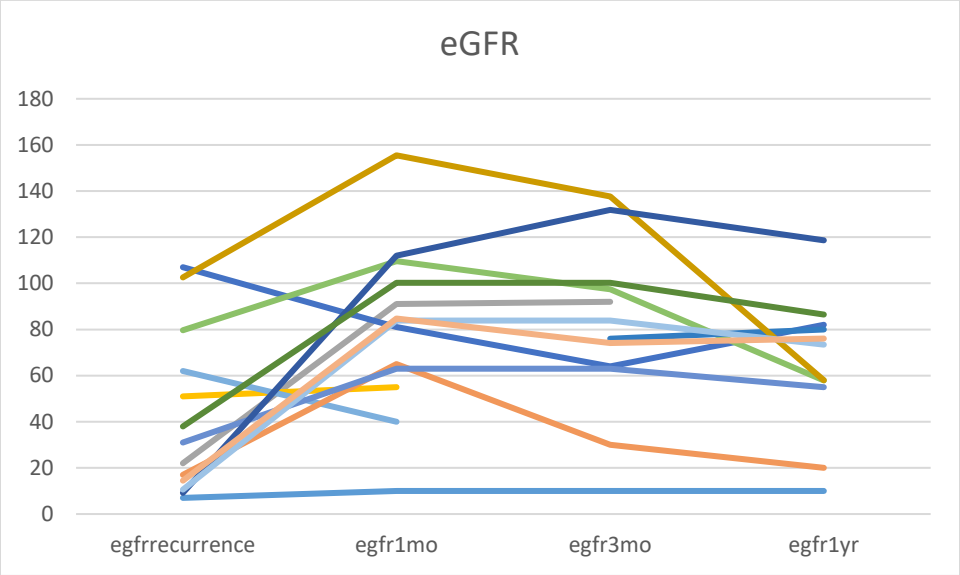


Figure 1b

Legend : eGFR trend over time showing overall improvement from the time of recurrence to 1 year



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Table 1: Demographics and clinical data

Age at diagnosis	12.7 (range 1 -59 yrs)
Age at transplant	21 (range 5.8-62 yrs)
Male	17 (68%)
Race Black Hispanic Caucasian Other	 3 9 11 3
Native biopsy findings FSGS Minimal Change disease Unknown Biopsy status unknown	23 13 9 1 3
Native nephrectomy performed	12(46.2%)
Deceased donor transplant living donor	13 (50%) 13 (50%)
Genetic testing	7 (26.9%)
Hemodialysis prior to transplant	17(65.4%)
Peritoneal dialysis prior to transplant	5 (19.2%)
No dialysis prior to transplant	4 (15.4%)
Recurrence of FSGS	
Median days after the transplantation	1 (range 1-652)
Methods of diagnosis available	24
By proteinuria	22 (84.6%)
By biopsy	2 (7.7%)

Table 2: TPE procedure details

	Post-transplant TPE	
Total number of patients	26	
Service prescribing apheresis Transfusion Medicine Nephrology Other Unknown	 18/26 (69%) 6/26 (23%) 1 (4%) 1 (4%)	
Access Central venous catheter AVF Port	 15/26 (59%) 9/26(35%) 2/26(6%)	

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TPE frequency First 4 weeks after recurrence Daily treatments Every other day Detail not available Median total number of daily TPE every other day TPE	First 4weeks after recurrence 6 /26 (23%) 12/26 (46%) 8/26 (31%) 3.5 (3-7) 7.5 (2-16)	
Total TPE procedures after the first 4 weeks	14 (2-109)	
Volume of replacement 1 plasma volume 1-1.5	 12 (46%) 14 (54%)	
Replacement fluid after 4 weeks Albumin FFP Combination of albumin and FFP	 24(92%) 0 2 (8%)	

Table 3: Complications with TPE, per procedure.

	In the first 4 weeks	After the first 4 weeks	
Allergic reactions	2/117 (1.7%)	1 /554 (0.18%)	
Suspected transfusion reactions	2/117 (1.7%)	1 /554 (0.18%)	
Hypocalcemia (only lab)	3/117 (2.5%)	1 /554 (0.18%)	
Other thrombosis		1 /554 (0.18%)	
Catheter associated infection		1 /554 (0.18%)	
Catheter not working and changed		1 /554 (0.18%)	
Prolonged infection		1 /554 (0.18%)	

Table 4: Details of additional treatments

Types of transplants Living donor Deceased donor	 13 13	
Immunosuppressive therapy Steroids, Rituximab, Abatacept, Cyclophosphamide	 25 9 1 1	

Table 5a: Response to treatment by proteinuria

	Recurrence	3 months	6 months
Urine protein/creatinine ratio mg/mg median(IQR)	4.47 (1.4,12.89)	1.4(0.22, 3.2)	1(0.27, 5.7)

Table 5b: Response to treatment by eGFR

	recurrence	3 months	1 year
Estimated GFR (ml/min/1.73m2) median (IQR)	26.5(14.4,62)	87.9(64,100)	78(63,86)

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Figure 1a:

Legend : Proteinuria as measured by urine protein/creatinine ratio (mg/mg) from a week after starting apheresis to 6 months after starting apheresis, showing response at 3 months but not sustained completely at 6 months

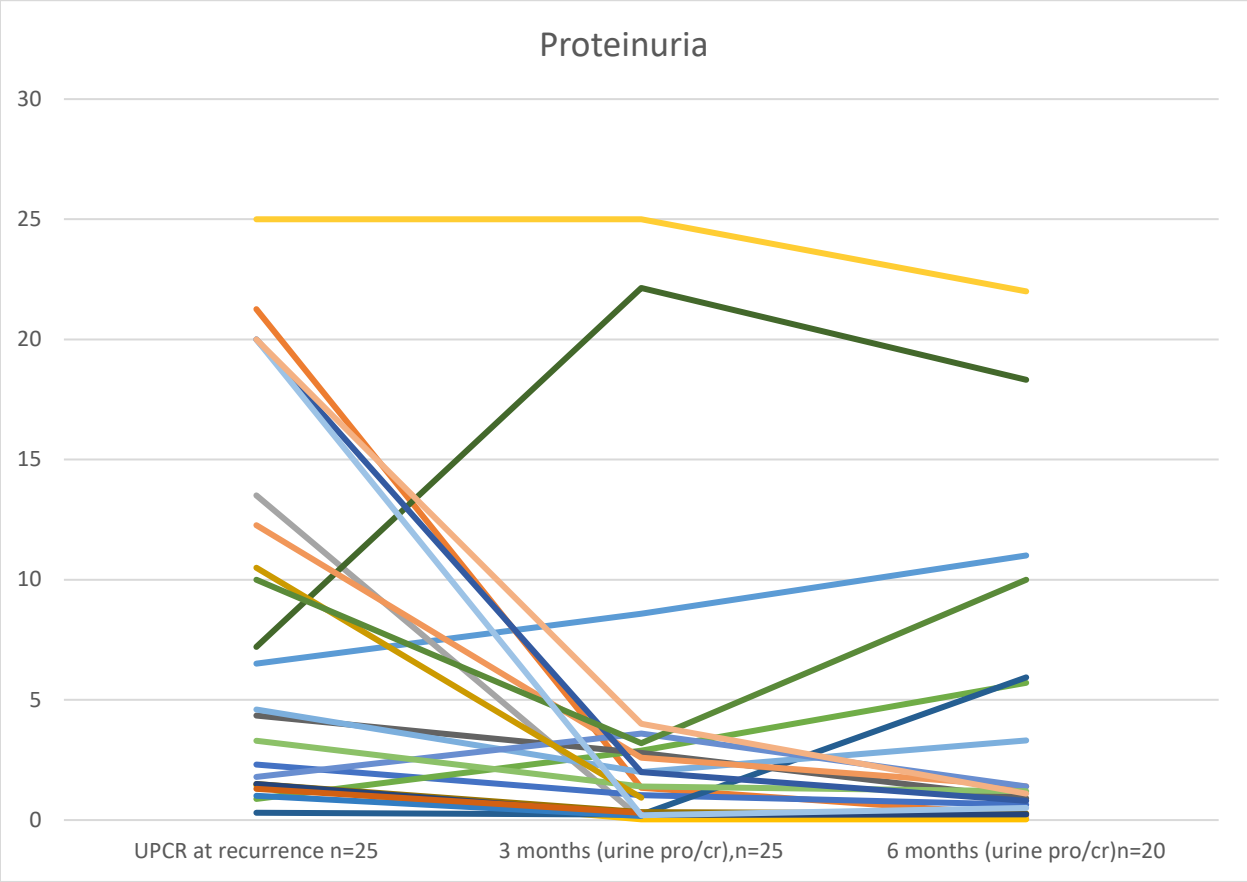


Figure 1b

Legend : eGFR trend over time showing overall improvement from the time of recurrence to 1 year

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