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End-Stage Renal Disease after Liver Transplantation in Patients with Pre-Transplant Chronic Kidney Disease

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Abstract

Renal dysfunction prior to liver transplantation has a marked impact on post-transplant kidney outcomes. The aim of this study was to assess post-transplant renal function in patients with chronic kidney disease (CKD) receiving orthotopic liver transplantation (OLT) alone.

METHODS—Retrospective review of 40 OLT recipients with pre-transplant CKD (serum creatinine ≥ 2 mg/dl for at least 3 months) at the University of Pennsylvania from February 2002 to July 2010. Primary outcome was estimated glomerular filtration rate (eGFR) up to 3 years post-transplant. Secondary outcomes included incidence of stage 4 CKD (eGFR < 30 ml/min), need for renal replacement therapy (RRT), meeting criteria for kidney transplant listing (eGFR ≤ 20 ml/min), and mortality.

RESULTS—Median patient age was 56.5 years and 48% patients had pre-transplant diabetes. Median serum creatinine at transplant was 2.7 mg/dl (eGFR 24 ml/min). Median eGFR at 1, 2, and 3 years post-transplant was 35, 34, and 37 ml/min respectively. Twelve patients (30%) required RRT at a median of 1.21 years posttransplant and 16 (40%) achieved an eGFR ≤ 20 ml/min at 1.09 years post-transplant. Mortality was 35% at a median of 1.60 years post-transplant.

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CONCLUSIONS—OLT recipients with pre-transplant CKD have a substantial burden of post-transplant renal dysfunction and high short-term mortality, questioning the rationale for OLT alone in this population.

Keywords

kidney dysfunction; liver transplantation; renal insufficiency

INTRODUCTION

Chronic kidney disease (CKD) is highly prevalent in liver transplant recipients and approximately 20% of patients undergoing liver transplantation develop stage 4 or 5 CKD at 5 years post-transplant.[1] CKD in liver transplant recipients is associated with a dramatic increase in cardiovascular risk, hospitalizations, and a 4 fold higher mortality compared to individuals with preserved renal function.[2–3] Both duration and degree of renal impairment prior to liver transplantation have been associated with progression of post-operative kidney disease.[4–7] Since the introduction of the Model for End-Stage Liver Disease (MELD) system for organ allocation in 2002, there has been a systematic increase in transplantation of patients with renal dysfunction and consequently, the number of simultaneous liver-kidney transplants (SLKT) has risen significantly.[8] However, there are limited data and no controlled studies to provide guidance regarding appropriate indications for dual organ transplantation in patients with pre-transplant kidney disease.[6,9] Given the limited organ pool, it is crucially important to effectively select patients best suited for SLKT based on extent and duration of renal dysfunction, need for renal replacement therapy (RRT), prediction of renal recovery post-transplant, and patient survival. This decision process has a significant impact on utilization of kidneys from deceased donors given uniformly long renal transplant waiting times. Furthermore, performing SLKT in patients likely to recover renal function is associated with higher operative risks and patients requiring RRT after OLT alone have impaired survival.[10]

There has been controversy in determining which liver transplant candidates with CKD should receive SLKT versus OLT alone. The consensus statement guidelines for SLKT candidacy have little data to guide what degree of CKD should initiate SLKT candidacy.[9] Additionally, fluctuating renal function before liver transplantation, and the impact of co-morbid conditions including diabetes and hypertension, well-established predictors of CKD, are not well accounted for in these recommendations, leading to a wide variety of approaches to SLKT selection at different centers. Using national data to assess post-transplant renal outcomes in patients with CKD receiving OLT alone is fraught with limitations due to lack of uniform practices among centers and a paucity of detailed post-transplant follow-up with respect to long-term kidney function. Our center has been aggressive in utilizing OLT alone for patients without strict indications for SLKT, providing data on post-transplant outcomes in patients with significant CKD in a region with high pre-transplant wait times and hence prolonged duration of pre-transplant kidney injury. The aim of our study was to assess post-liver transplant renal function in patients with substantial pre-transplant CKD in order to determine predictors of poor outcomes in this cohort.

METHODS

We performed a retrospective analysis of 40 patients with pre-transplant CKD, defined as a serum creatinine of 2 mg/dl or higher for at least 3 months prior to transplant, who received liver transplantation alone at the University of Pennsylvania between February 2002 and July 2010. A start date of February 2002 was chosen to coincide with the implementation of the MELD system for organ allocation. Patients with fulminant hepatic failure, prior liver

transplantation, and those without adequate pre-transplant data to determine duration of CKD were excluded from our study.

For those subjects eligible for inclusion, patient information was obtained from a prospectively maintained electronic database, OTTR (Organ Transplant Tracking Record), as well as inpatient charts for all transplants performed at our center. Institutional review board approval was obtained prior to study initiation.

Demographic data was collected on all patients including age, race, gender, etiology of liver disease, diabetes (pre-transplant as well as de-novo after transplantation), hypertension (pre and post-transplant), the presence of hepatocellular carcinoma (HCC), serum albumin, calculated MELD score at transplant, serum creatinine, serum bilirubin, serum INR, and requirement for pre-transplant renal replacement therapy. Post-transplant data collected included renal function as well as liver and non-liver related mortality.

The primary outcome assessed in our study was estimated glomerular filtration rate (eGFR) measured with the Modification of Diet in Renal Disease (MDRD) equation, an equation used for the estimation of the glomerular filtration rate with serum creatinine combined with age, gender and race[11] at 1 year, 2 years, and 3 years in order to determine the incidence of post-transplant CKD. The incidence of stage 4 CKD (defined as an eGFR < 30 ml/min), need for RRT, meeting criteria for kidney transplant listing (eGFR ≤ 20 ml/min), and mortality were also assessed in our patient cohort. These data were also collected in SLKT recipients at our institution in order to assess post-transplant outcomes including renal function and mortality in this cohort as a comparison group, although one with greater severity of pre-transplant renal disease.

In order to account for fluctuating renal function in the 3 months prior to transplantation, we performed additional analyses to determine a time-weighted mean eGFR. This was done in order to distinguish between individuals with differing durations and magnitudes of change in pre-transplant renal function and assess the impact on post-transplant kidney outcomes, as described in a recent publication by Rueber et al.[12]

STATISTICAL ANALYSIS

For continuous variables, we reported means for normally distributed variables and medians for non-normally distributed variables. These were compared with Student t-tests or rank sum tests, as dictated by their distribution. Categorical variables were reported as percentages and compared with Chi-square and Fisher's exact testing as appropriate. Kaplan-Meier analysis was performed to determine the time to eGFR ≤ 20 ml/min, renal replacement therapy, and death. All patients were censored at the end of follow-up. For eGFR analysis post-transplant, patients on dialysis were conservatively assigned an eGFR of 15 ml/min.

Cox proportional hazards were utilized to assess for predictors of the need for post-transplant RRT in univariate and multivariate analyses. Given the sample size and hence limited number of events, all multivariate models were limited to the inclusion of 2 clinical predictors. All analyses were performed using STATA version 11.2 (Stata Corp College Station, Texas). A p-value of less than 0.05 was considered statistically significant.

RESULTS

Among 1031 liver transplant recipients at our institution between February 2002 and July 2010, 40 OLT alone recipients had evidence of pre-transplant CKD, and were included in our study. The median age of the cohort was 56.5 years [interquartile range (IQR) 52–60.5],

80% of the patients were male, and 75% were Caucasian. Of these, nineteen patients (48%) had pre-transplant diabetes and 24 (60%) had hypertension; 53% patients had Hepatitis C infection as the etiology of liver disease, and 20% had hepatocellular carcinoma. The median calculated MELD score at transplant was 26; median serum bilirubin was 3.2 mg/dl, INR was 1.6, albumin was 2.6 g/dl, and median serum creatinine was 2.7 mg/dl. The median eGFR was 24 ml/min at the time of transplant and 18% of the cohort required dialysis for a mean duration of 13 days prior to transplantation (Table 1).

On assessment of time-weighted eGFR, 10 patients (25%) had a mean time-weighted eGFR pre-transplant of < 30 ml/min, 25 patients (63%) had a mean time-weighted eGFR between 30 and 45 ml/min, and 5 patients (12%) had a mean time-weighted eGFR between 45 and 60 ml/min within 3 months prior to transplantation.

With regard to post-transplant renal outcomes, the median eGFR at 1, 2 and 3 years post-transplant was 35 ml/min, 34 ml/min and 37 ml/min, respectively. Fifty three percent of the cohort developed stage 4 CKD (eGFR < 30 ml/min) at 3 years post-transplant (Table 2).

Twelve patients (30%) required permanent RRT at a median follow-up of 1.21 years post-transplant; one additional patient received RRT for acute kidney injury in the setting of sepsis. The median pre-transplant serum creatinine was 2.5 mg/dl in this group and 3 of the twelve patients were on dialysis prior to transplantation. The majority of patients requiring chronic RRT post-transplant had diabetes mellitus (75%) and/or hypertension (75%). Two patients received kidney transplantation during our follow-up period and 16 patients (including those on dialysis) achieved an eGFR ≤ 20 ml/min at a median of 1.09 years post-transplant. Among the 10 patients with a mean time-weighted eGFR pre-transplant of < 30 ml/min, 3 required post-transplant RRT at a median of 22 days post-transplant.

Pre-transplant diabetes was a significant predictor of post-transplant RRT on univariate analysis (HR 4.23, 95% CI 1.12–15.93, p 0.03). African American race was a significant predictor when compared to Caucasians (HR 3.44, 95% CI 1.04–11.35, p 0.04). In a multivariate model including diabetes mellitus and African American race, the association between pre-transplant diabetes and post-transplant RRT was of borderline significance (HR 3.50, 95% CI 0.89–13.75, p 0.07). Hypertension (*p* 0.24), serum creatinine (*p* 0.98), Hepatitis C infection (p 0.12), pre-transplant RRT (*p* 0.40), MELD score (p 0.30), pre-transplant eGFR (p 0.31), and weighted mean eGFR (p 0.64) were not predictors of post-transplant RRT on univariate analysis.

Fourteen patients (35%) died at a median of 1.60 years post-transplant; six deaths were attributable to sepsis and one to liver failure. Four patients who died were on permanent RRT post-transplant.

In comparison, there were 48 SLKT recipients at our institution during the study period specified; 16 patients were excluded as they had received prior transplants hence we assessed outcomes in 32 patients. The median age in the SLKT cohort was 53 years, 81% patients were male, 47% had pre-transplant diabetes mellitus and 56% had hypertension. Fifty percent of dual organ transplant recipients (16 patients) were on chronic RRT prior to transplant and the median MELD score at transplantation was 27. The median eGFR at 1, 2, and 3 years post-transplant was 55 ml/min, 53 ml/min and 54 ml/min respectively; five patients (16%) developed stage 4 CKD during median follow-up of 3.07 years post-transplant. Five patients achieved an eGFR ≤ 20 ml/min at a median of 1 year post-transplant; one patient was unable to come off dialysis after transplantation and required chronic RRT. Twelve patients (38%) in the SLKT cohort died at median of 1.52 years post-transplant.

DISCUSSION

The MELD score was implemented for liver transplant allocation in order to allow for candidates with the highest predicted pre-transplant mortality and thus the greatest need to receive organs. Given the heavy weighting of serum creatinine in the MELD equation, there has been an increase in liver transplant recipients with kidney disease since MELD implementation,[13] as well as a dramatic rise in SLKT in order to optimize outcomes. However, early survival is worse in patients undergoing SLKT compared to OLT alone, indicative of the greater magnitude of the surgery and greater burden of comorbidities in this cohort. There is significant uncertainty regarding renal recovery post-transplant even in patients requiring RRT prior to transplantation as many patients spontaneously recover renal function after liver transplantation, particularly those with hepatorenal syndrome.[14–15] This has fuelled debate in the transplant community about the optimal utilization of kidney transplants given the limited number of organs.

Determining the severity of renal dysfunction is also a challenge in patients with chronic liver disease. It is widely recognized that serum creatinine is unreliable in estimating renal function accurately in patients with cirrhosis due to lower muscle mass, decreased hepatic synthesis of creatine (a precursor to creatinine), and increased creatinine secretion by the renal tubules, leading to an overestimation of renal function.[6] Additionally, although renal biopsies are helpful in determining the cause and extent of kidney disease, percutaneous and transjugular kidney biopsies in patients with coagulopathy and thrombocytopenia carry significant risks, limiting their use in this population.

The results of our study confirm poor renal outcomes in patients with advanced CKD undergoing OLT alone with a high rate of renal dysfunction after transplant. Twelve patients (30% of the cohort) required chronic RRT at a median of 1.21 years post-transplant and 40% of patients achieved an eGFR of 20 ml/min or less at a median of just 1.09 years after transplantation. These patients qualified for listing for a kidney transplant soon after liver transplantation; however, there is currently no priority kidney transplant allocation for such patients and only 2 liver transplant recipients received kidney transplants during our follow-up period. This raises an important issue of qualification for SLKT in these patients. The vast majority of patients in our study were evaluated by transplant nephrology and determined not to require dual organ transplantation based on the extent of their kidney disease and the strict institutional policy regarding SLKT criteria, belying the difficulty in predicting renal outcomes in advance based on available guidelines. These recommendations stipulate dual organ transplantation for patients with an eGFR < 30 ml/min for 3 months or longer.[9] These guidelines do not speak to whether the eGFR must be < 30 ml/min for the entirety of this period or whether a weighted average is more appropriate. However, only 10 patients in our cohort (25%) had a weighted mean eGFR of < 30 ml/min within 3 months prior to transplantation, and weighted mean eGFR was not a predictor of post-transplant RRT in our cohort (p 0.64). Additionally the consensus guidelines do not account for the impact of diabetes, African American race, or acute on chronic kidney injury in deciding on appropriate candidates for SLKT. Diabetes and African American race were associated with a higher risk of advanced CKD post-transplant in our analysis; however, given the small sample size, the impact of diabetes and race were unable to be explored in the context of other predictors.

The high mortality in our patient cohort is extremely concerning. There were 14 deaths (35%) at a median of 1.60 years post-transplant. Six patients died due to sepsis and 1 patient died from liver failure. It is hard to determine if these patients would have had lower post-transplant mortality in the setting of SLKT. In comparison, the mortality in the SLKT cohort during our study period was 38% (12 patients) at a median of 1.52 years post-transplant;

four of these patients died of sepsis, and two had liver failure. Our results do not demonstrate a significant difference in post-transplant survival between those who underwent SLKT and those who received OLT alone. This might be attributable to the significantly higher burden of renal disease in our SLKT cohort, whose median serum creatinine at transplant was 4 mg/dl (50% patients were on chronic RRT pre-transplant). A prior study by Schmitt et al analyzing United Network for Organ Sharing data from 2002 to 2006 demonstrated no mortality benefit with SLKT in patients who had a serum creatinine > 2.5 mg/dl pre-transplant.[10] Eleven of the twelve deaths in our SLKT cohort occurred in patients with pre-transplant serum creatinine levels > 2.5 mg/dl; six of these patients died within 1 year post-transplant. While organ scarcity has limited the number of patients at our center who receive SLKT, the long term survival benefit appears to be lost in patients with advanced pre-transplant CKD who are selected for SLKT. A recent analysis comparing SLKT versus OLT alone also revealed that SLKT might be more protective on post-liver transplant survival among patients with a pre-transplant eGFR between 30 and 60 ml/min (HR 0.41, *p* 0.05) compared to those with an eGFR < 30 ml/min (HR 0.73, *p* NS).[16] Prolonged wait list times in our region and hence longer duration of pre-transplant CKD have a substantial impact on post-transplant outcomes. Additionally, the comorbid conditions in both the SLKT and OLT alone groups with substantial CKD in our cohort are significant, in part due to center practice, Organ Procurement Organization characteristics, as well as the high MELD score at transplantation in our region. These comorbid conditions may explain the higher than expected mortality in this particular group, given that the overall post-transplant mortality based upon case mix and complexity over this time period was not higher than expected at our center.

In the SLKT patients who survived, the incidence of post-transplant CKD was much lower than the OLT alone group with a median eGFR at 3 years of 54 ml/min versus 37 ml/min, respectively, despite worse pre-transplant renal function in this cohort. Only 5 patients in the SLKT cohort (16%) developed severe CKD meriting kidney transplant listing (eGFR ≤ 20 ml/min) compared to 16 patients (40%) in the OLT alone group.

We chose a pre-transplant serum creatinine of 2 mg/dl or higher as our inclusion criteria as this threshold has been shown to be associated with worse renal function after liver transplantation.[17] This is a simple and easily accessible laboratory value that can be assessed in all patients, as opposed to complex renal clearance tests including the MDRD calculation, which have not been shown to be very accurate in patients with cirrhosis. Furthermore, we selected patients with an elevated serum creatinine for at least 3 months pre-transplant as prior work at our institution has identified worse outcomes in patients with renal dysfunction for 12 weeks or longer prior to liver transplantation.[17]

Limitations of our study include its retrospective nature as well as incomplete information regarding the precise duration of pre-transplant CKD in patients who already had renal dysfunction upon referral for liver transplantation. Furthermore, we defined CKD based on serum creatinine, an imperfect estimate of kidney function as described above in patients with chronic liver disease. Nonetheless, the median eGFR at the time of transplant was 24 ml/min in our cohort, suggesting significant pre-transplant renal injury. An additional limitation of our study includes the uniform nature of immunosuppression in our cohort. We utilize tacrolimus-based immunosuppression with slightly diminished target levels in patients with renal dysfunction but do not systematically alter immunosuppression regimen in these patients long term, limiting the ability to assess different strategies of immunosuppression. Additionally, there is absolutely no standardization or goal trough level that is aimed for in this cohort and adjustments are made at the physicians' discretion. We also acknowledge that this is a single center study with limited sample size and our results

may not be generalizable to other institutions; however, the quality and detail of the data pertaining to renal function is superior to nationalized database analyses.

In summary, our findings suggest that patients with pre-transplant CKD have poor post-transplant renal function and a high mortality when receiving OLT alone. These patients would not clearly be eligible for SLKT by current published guidelines as we interpret them. Renal outcomes were substantially better in the SLKT group compared to the OLT alone group. The high mortality in both the OLT alone and SLKT groups does demonstrate the higher comorbid medical disease in patients with combined advanced liver and renal disease, as well as prolonged duration of kidney injury due to long wait-times for transplantation in our region, and highlights the need for careful attention to recipient selection in considering which of these patients are favorable candidates for transplantation at all. From a renal function perspective, our data does not support proceeding with OLT alone in this patient group, particularly in patients with pre-transplant diabetes, a factor which needs further study. However, our data does not clearly show that SLKT in these patients would necessarily afford better post-transplant outcomes either, albeit this comparison cohort had a greater burden of renal disease and was not a true control population. It is possible that new advances in biomarker research will allow for determination of renal recovery potential in this patient group without the risk of renal biopsy, but this technology is not clinically developed at this time. Until then, further protocolized multicenter trials are needed to refine the guidelines regarding SLKT candidacy in patients with pre-transplant CKD as the application of current guidelines leads to unsatisfactory renal outcomes.

Abbreviations

CKD	chronic kidney disease
eGFR	estimated glomerular filtration rate
HCC	hepatocellular carcinoma
IQR	interquartile range
MDRD	Modification of Diet in Renal Disease
MELD	Model for End-Stage Liver Disease
NASH	Non Alcoholic Steatohepatitis
OLT	orthotopic liver transplantation
OTTR	Organ Transplant Tracking Record
RRT	Renal Replacement Therapy
SLKT	simultaneous liver-kidney transplant
UNOS	United Network for Organ Sharing

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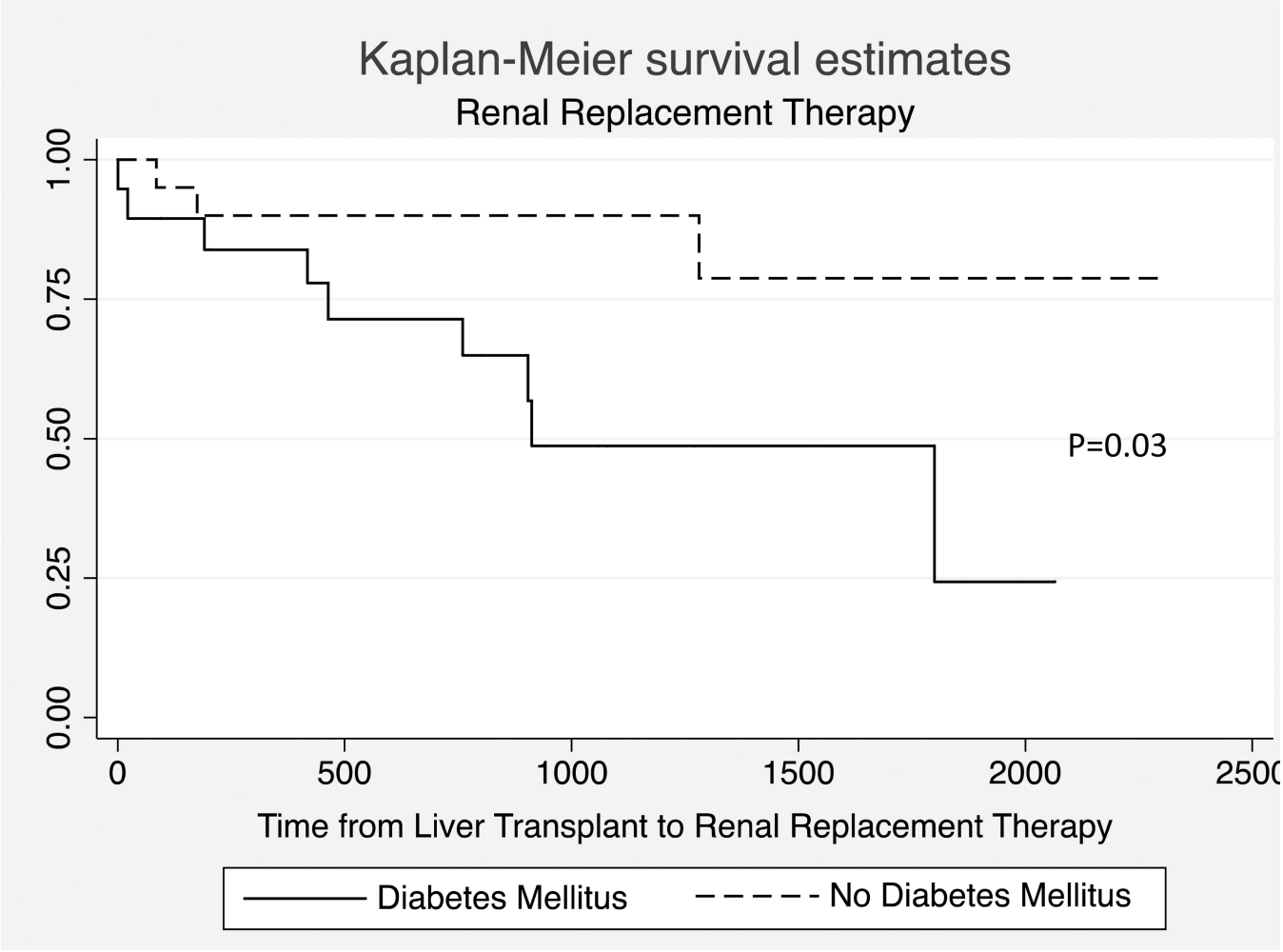

Figure 1.
Kaplan-Meier survival estimate of time to RRT: Impact of Pre-Transplant Diabetes

Table 1

Baseline Demographics

Median Age (IQR)	56.5 (52–60.5)
Gender	Male 32 (80%) Female 8 (20%)
Race	Caucasian 30 (75%) African American 8 (20%) Hispanic 2 (5%)
Hypertension	24 (60%)
Diabetes Mellitus	19 (48%)
Etiology Liver Disease N (%)	Hepatitis C 21 (53%) Hepatitis B 2 (5%) Alcoholic Liver Disease 10 (25%) Autoimmune Liver Diseases 2 (5%) NASH 2 (5%) Cryptogenic 3 (7%)
HCC N (%)	8 (20%)
Renal Replacement Therapy Pre-transplant N (%)	7 (18%)
Median Albumin (g/dl)	2.6 (2.2–3.1)
Median Bilirubin (mg/dl)	3.2 (1.5–5.1)
Median Creatinine (mg/dl)	2.7 (2.1–3.7)
Median eGFR (ml/min)	24 (16–33)
Median INR	1.6 (1.4–2)
Median MELD	26 (22–31)

Table 2

Post-Transplant Renal Outcomes after Liver Transplantation

Median eGFR at 1 year (ml/min) (IQR)	35(27–47)
Median eGFR at 2 years (ml/min) (IQR)	34(20–51)
Median eGFR at 3 years (ml/min) (IQR)	37 (22–55)
eGFR < 30 ml/min N (%)	21(53%)
eGFR ≤ 20 ml/min N (%)	16 (40%)
Renal Replacement Therapy N (%)	12 (30%)