Meeting Report

Proceedings of Consensus Conference on Simultaneous Liver Kidney Transplantation (SLK)

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A consensus conference sponsored by the American Society of Transplant Surgeons (ASTS), American Society of Transplantation (AST), United Network for Organ Sharing (UNOS) and American Society of Nephrology (ASN) convened to examine simultaneous liver-kidney transplantation (SLK). Directors from the 25 largest liver transplant programs along with speakers with recognized expertise attended. The purposes of this conference were to propose indications for SLK, to establish a prospective data registry and, most importantly, to recommend standard listing criteria for these patients. Scientific registry of transplant recipients data, and single center data regarding chronic kidney disease (CKD) and acute kidney injury (AKI) in conjunction with liver failure as a basis for SLK was presented and discussed. The consensus was that Regional Review Boards (RRB) should determine listing for SLK, as with other MELD exceptions, with automatic approval for: (i) End-stage renal disease with cirrhosis and symptomatic portal hypertension or hepatic vein wedge pressure gradient $\geq$ 10 mm Hg (ii) Liver failure and CKD with GFR $\leq$ 30 mL/min (iii) AKI or hepatorenal syndrome with creatinine $\geq$ 2.0 mg/dL and dialysis $\geq$ 8 weeks (iv) Liver failure and CKD and biopsy demonstrating $>$ 30% glomerulosclerosis or 30% fibrosis. The RRB would evaluate all other requests to determine appropriateness.

Key words: Combined transplants, kidney transplantation, liver transplantation

Abbreviations: OLT, orthotopic liver transplantation; MELD, model of end-stage liver disease; SLK, simultaneous liver-kidney; ESLD, end-stage liver disease; UNOS, united network for organ sharing; SRTR, scientific registry of transplant recipients; AKI, acute kidney injury; HRS, hepatorenal syndrome; ESRD, end-stage renal disease; LTA, liver transplant alone; CKD, chronic kidney disease; NKF, national kidney foundation; eGFR, estimated glomerular filtration rate; HCV+, hepatitis c positive; KTA, kidney transplant alone; RRB, regional review board.

Introduction

One of the greatest challenges facing orthotopic liver transplantation (OLT) today is pre and posttransplant renal dysfunction. Serum creatinine is a predictor of posttransplant outcome, and kidney injury is the greatest determinant of mortality (1,2). Since the institution of the model of end-stage liver disease (MELD) system in 2002, the number of simultaneous liver-kidney transplants (SLK) has increased over 300%. The primary issue is to balance benefit and utility to assure that patient and graft survival is optimized while limiting unnecessary transplants. A recent consensus conference convened to establish guidelines for evaluation, listing and transplantation of patients with end-stage liver disease (ESLD) and renal failure. A second purpose was to establish a registry to study criteria important in determining propriety of SLK. Finally, this group was charged with proposing standard listing criteria for SLK to United Network for Organ Sharing (UNOS).

Scientific Registry of Transplant Recipients (SRTR) Data (3)

Conferees reviewed SRTR data for adult candidates added to the liver waiting list from the start of the MELD system (2/27/02) until July, 2007. The number of candidates and recipients of SLK has accelerated since 2002. In 2001 there were 228 candidates and 134 recipients, compared with 585 and 400, respectively in 2006 and 567 candidates and 444 recipients in 2007. The variation among centers of the percentage of SLK transplants ranged from 0% to 43.7% of all OLT (Figure 1).
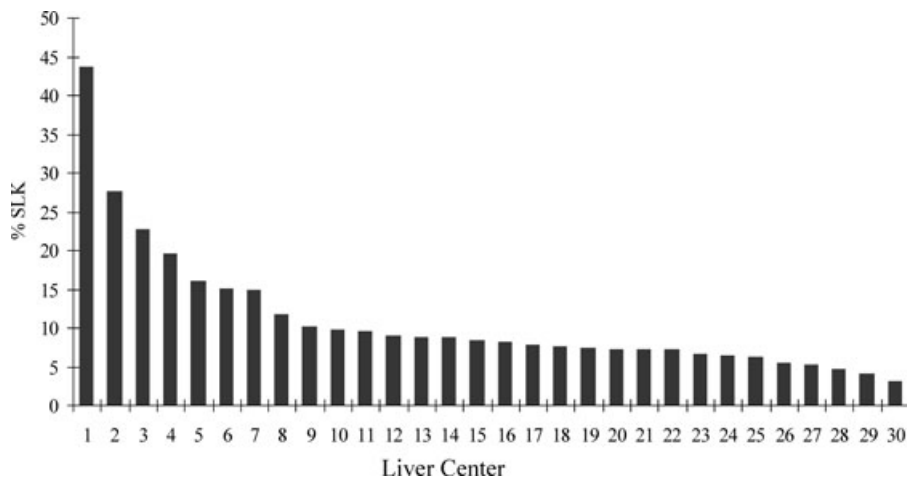
Figure 1: Percentage of liver transplants that were SLK transplants by center for 30 largest SLK centers, 1/1/2004– 6/30/2006.

Approximately 7% of all OLT candidates were on dialysis, listed for SLK, or both. Of all OLT recipients, 8.2% were on dialysis at transplant and 6.1% received an SLK. Over 40% of SLK recipients were not on dialysis at transplant. Among SLK candidates, over half had concurrent liver and kidney listings, 36% had a liver listing followed by a kidney listing and 7% had a kidney listing followed by a liver listing. The primary renal diagnosis was acute kidney injury/hepatorenal syndrome (AKI/HRS) in only 2% of SLK recipients, with the diagnosis not specified in over 38%. Therefore, the true prevalence of end-stage renal disease (ESRD) in SLK candidates is unknown. Among liver transplant alone (LTA) candidates on dialysis at listing, 67 of 428 were not on dialysis at transplant. Among SLK candidates, 41 of 634 on dialysis at listing were not on dialysis at transplant and 509 of 688 not on dialysis at listing were not on dialysis at transplant. The respective MELD scores at listing and at transplant for the four groups were 15 and 18 for LTA no dialysis, 31 and 39 for LTA on dialysis, 24 and 25 for SLK no dialysis and 27 and 31 for SLK on dialysis.

Liver candidates on dialysis or listed for SLK, had increased waiting list mortality (Figure 2A). Although LTA candidates on dialysis at listing had the greatest short-term mortality, their subsequent survival was similar to LTA candidates not on dialysis. In contrast, although SLK candidates (whether on dialysis or not) had better short-term survival while on the wait list than LTA candidates on dialysis, their survival was worse over the entire period. Listing of candidates with renal dysfunction for LTA presumably reflects reversible renal dysfunction caused by liver disease, in contrast to the heterogeneous nature of renal dysfunction and liver disease severity in SLK candidates. While lesser degrees of renal dysfunction than dialysis correlated with unadjusted LTA waitlist mortality, this was less significant for SLK candidates.

Posttransplant survival for LTA recipients on dialysis was lower than that for SLK recipients on dialysis (Figure 2B), with a two-year survival of 75.9% for SLK and 70.8% for LTA on dialysis at the time of transplant. Whether this re-
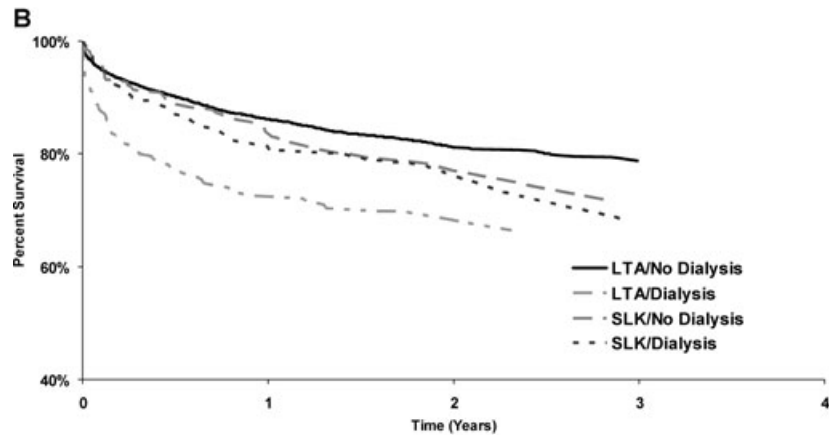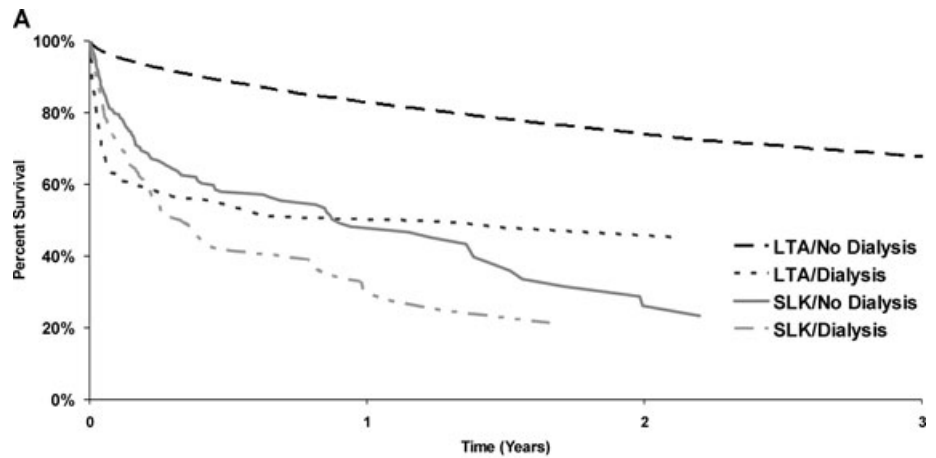
flects an advantage conferred by the kidney transplant or reflects differences in liver disease severity, or duration or cause of renal dysfunction between SLK and LTA recipients cannot be determined. Approximately 12% of SLK candidates received a LTA; however, these LTA recipients who were originally listed for SLK had inferior posttransplant survival. Whether these candidates received a LTA based on medical urgency, borderline kidney indications, or donor issues is unknown, but could bias these outcomes.

As a measure of short-term renal outcome after transplant, the need for a kidney transplant after LTA or SLK was found to be uncommon. Only 8 (2.4%) of 331 LTA and 6 (2.5%) of 237 SLK recipients on dialysis at transplant were listed for, or received a kidney transplant within one year of OLT. The three-year outcomes of kidney after liver transplant suggest that patient survival (counted from the time of kidney transplant) is superior to patient survival after SLK (Figure 3), but inferior to that of kidney only recipients.
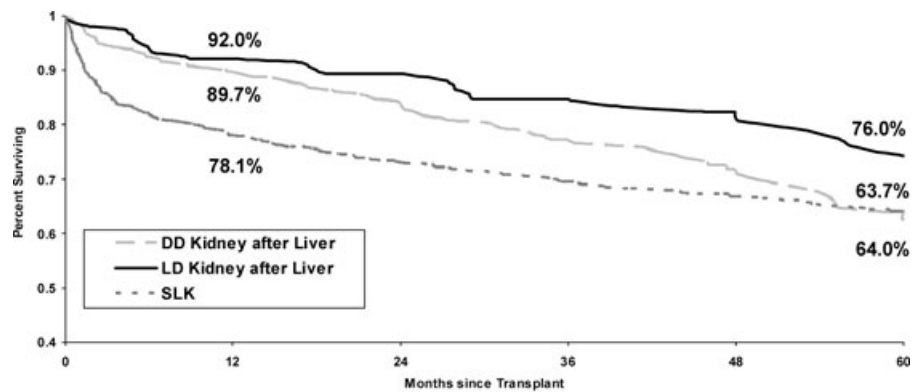
While duration of dialysis can be ascertained for those receiving SLK or those who begin dialysis after listing, duration of dialysis for LTA recipients who are listed on dialysis is not ascertainable. Thus, determining the duration of renal insufficiency and dialysis that predicts renal failure after LTA is not possible.

Evaluation of the Prospective SLK Candidate

All liver transplant candidates should be evaluated according to the algorithm published from the first consensus conference (2). Prospective recipients should be categorized as having AKI or chronic kidney disease (CKD) determined by the definitions developed by the AKI Network and Acute Dialysis Quality Initiative Group and the National Kidney Foundation (NKF) guidelines (4–8). Once a patient is on the waiting list, kidney function should be assessed at least at the time points required to confirm MELD status. Cystatin C is a more accurate marker of renal function than

Figure 2: (A) Unadjusted waiting list (WL) survival by kidney listing and dialysis status (2/27/02–6/30/05) (B) survival of recipients listed for liver-kidney by type of organ received and dialysis at transplant (Tx) (2/27/02–6/30/05).

*Patients were listed and transplanted during this time period

Figure 3: Patient survival (from Kidney transplant [Ktx]) for kidney after liver and kidney only transplant.

*Survival time since kidney transplant
DD: deceased donor
LD: living donor

serum creatinine, however it is not universally available and is not part of the MELD assessment paradigm (9).

Intrarenal fibrosis is associated with progression to ESRD. Thus if there is more than 30% interstitial fibrosis, the OLT candidate should receive SLK. Glomerulosclerosis of more than 30% is also a marker for CKD and thus can be used as a criterion for SLK selection; however, it is not as powerful a predictor as interstitial fibrosis. Patients with an estimated glomerular filtration rate (eGFR) less than 30 cc/min with a

chronic course should undergo biopsy. Biopsy at the time of OLT would also be timely enough to help in the decision for SLK. If a biopsy is not possible then the decision to perform a kidney transplant should be made using the NKF criteria of CKD, which is an eGFR less than 30 cc/min for more than 3 months. The key is to be able to determine which patient has irreversible kidney failure. In order to assess the results of these parameters, a renal scan with MAG-3 agent between 3 to 6 months after SLK along with eGFR should be performed to determine the function of the native and transplanted kidneys.

End-Stage Renal Disease (ESRD) with Cirrhosis

There is a paucity of data regarding the need for OLT in ESRD patients with asymptomatic liver disease including Child's A cirrhosis. This issue is important because of the incidence of Hepatitis C Positive (HCV+) in dialysis patients of 10–40%, coupled with the fact that ESRD patients have a MELD score of 21 with normal bilirubin and international normalized ratio (INR) (10, 11). However, the question remains whether these patients are best served with kidney transplant alone (KTA) versus SLK. In a study of HCV+ ESRD patients, a higher risk of mortality was seen in patients with stage 3 or 4 fibrosis undergoing KTA (12). However, these patients had better survival than those remaining on dialysis. A more recent study looked at 58 HCV+ patients undergoing KTA (10). This study found that mortality in ESRD patients undergoing KTA was not related to the degree of liver disease but rather by the presence of other comorbidities, namely, diabetes and advanced age. Some patients with Child's A cirrhosis can be treated and remain

asymptomatic for years, and thus may be well-served by receiving KTA (13). The determination of SLK versus KTA must be based on liver histology and signs of portal hypertension with wedge hepatic vein pressure being the gold standard (14). A proposed algorithm for selection for SLK listing in these patients is demonstrated in Figure 4.

Special Patient Considerations for SLK

Three patient categories were discussed that could influence the decision to perform SLK: (i) older patient age; (ii) patients with impaired kidney function at the time of OLT; and (iii) patients requiring retransplantation.

(i) Older age
While the life expectancy benefit of KTA over dialysis is lost as patients approach 70 years, several reports indicate that age alone does not compromise outcomes in OLT. A recent UNOS data analysis examined the effect of age and pretransplant dialysis on OLT survival (15). For both LTA and SLK recipients dialyzed pretransplant, one-year survival was reduced in patients older than 65 compared to their younger counterparts (for LTA, 50.7% vs. 77.8%; for SLK, 67% vs. 82.5% respectively). Using as a reference LTA recipients less than 65 not on pretransplant dialysis, investigators found that mortality was increased in older, non-dialyzed recipients (HR 1.36), as well as in all patients requiring dialysis before transplantation (HR 4.4 and 1.71 respectively for older and younger LTA recipients; HR 3.38 and 1.18 for older and younger SLK recipients respectively). Given the unfavorable outcomes in older liver candidates on dialysis, selection of such patients for SLK warrants careful consideration.
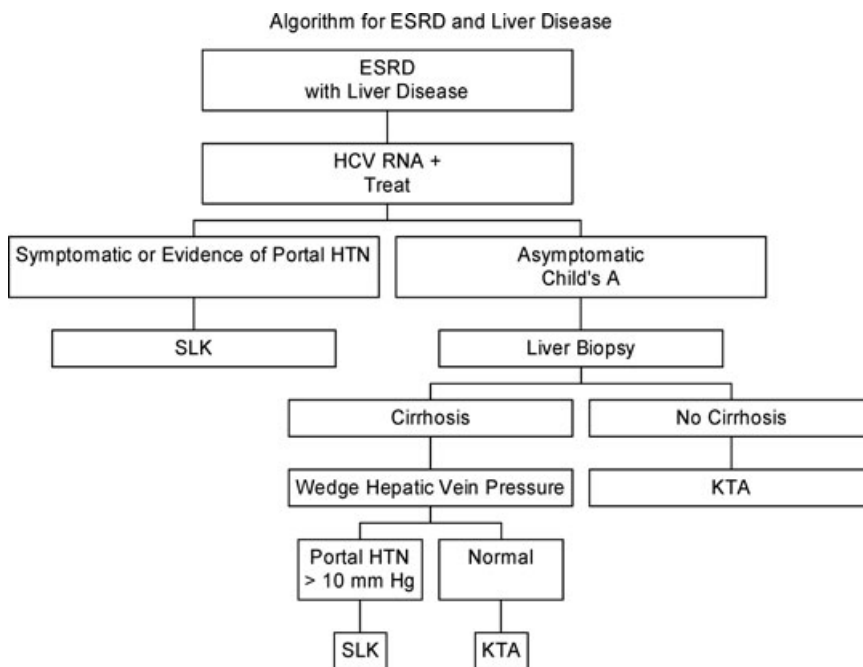

Figure 4: Algorithm for ESRD with cirrhosis.

(ii) Impaired kidney function at transplantation

SLK may benefit some liver candidates with either concomitant ESRD or risk of progression to advanced CKD soon after liver transplantation. The fact that most studies have not characterized kidney dysfunction (AKI, CKD, AKI superimposed on CKD) at the time of OLT undermines SLK patient selection. Commonly-cited grounds for SLK in liver candidates with kidney dysfunction are that: compared to LTA, SLK improves survival; and pretransplant AKI can be irreversible, leading to chronic dialysis or kidney transplantation. The first reason has been refuted in a UNOS data analysis (16), where candidates not on dialysis but with a creatinine above 2 mg/dL at transplant, had similar 3-year survival regardless of whether they received LTA or SLK.

In addition to the degree of kidney impairment, the duration of pre-OLT kidney dysfunction may predict posttransplant kidney function (17). While most LTA recipients with pretransplant kidney dysfunction do not progress to consideration for kidney transplantation (eGFR < 20 mL/min) by 3 years posttransplant, there is a significant number who will. (18). Sixty OLT recipients with kidney impairment pretransplant were compared according to duration of dysfunction (< or > 12 weeks). Pretransplant kidney dysfunction greater than 12 weeks strongly predicted a posttransplant eGFR <20 mL/min. This endpoint was reached in eight (13%) patients, of whom six were in the cohort with prolonged pretransplant kidney dysfunction. More significantly, 95% of patients with shorter and 74% of patients with longer duration pretransplant kidney dysfunction had an eGFR above 20 mL/min by 3 years posttransplant.

Recent data from Baylor University Medical Center aimed at identifying patients at risk for ESRD after OLT was presented. Although level of pretransplant kidney function predicted posttransplant CKD, no factors predictive of chronic dialysis or kidney transplantation were detected (19). There was also no evidence that LTA followed by kidney transplant was deleterious. These findings corroborated SRTR data, demonstrating that survival in the setting of sequential kidney after liver transplantation was similar to that after SLK (20,21).

A study examining kidney outcomes in SLK recipients with HRS, demonstrated no differences in posttransplant dialysis requirement, or three-year survival between patients with (n = 22) and without (n = 76) HRS (22). All HRS patients required pretransplant dialysis, mostly beyond 30 days. These investigators also identified 148 LTA recipients who had HRS at transplant. Of these patients, 80 required pretransplant dialysis, for less than 30 days in all cases. The investigators compared outcomes between these 80 LTA recipients and the 22 SLK patients with HRS described above. One year survival was not significantly different between the OLT and SLK cohorts. In the LTA group, dialysis was required in 89% of patients posttransplant yet only 8 needed dialysis beyond 30 days;

and 3 required long-term dialysis. Therefore, over 90% of dialyzed HRS patients recovered renal function after OLT. Data from Baylor similarly indicated that patients with HRS on dialysis for less than 4 weeks should receive a liver only.

For patients not on dialysis at the time of OLT: SLK should only be considered in patients who have an eGFR <30 mL/min and criteria for CKD as defined by National Kidney Foundation (i.e. duration more than 90 days). This eGFR threshold was proposed based on data demonstrating that the MDRD formulae overestimate the actual GFR in OLT candidates (23). It was also advised that liver candidates should be educated regarding possible posttransplant CKD and consideration living donor kidney transplant following OLT. For patients with either AKI /HRS, SLK should not be considered based on (i) the absence of studies showing meaningful benefit compared to OLT for this population; (ii) the potential for some reversibility to the acute injury component; and (iii) data demonstrating a low likelihood of progressive CKD in the first few years after OLT. A biopsy was suggested as a potentially helpful adjunct in some settings, although the prognostic value in this setting is not well established.

For patients on dialysis at the time of OLT: SLK is recommended for patients with established ESRD. For liver candidates requiring dialysis in the setting of AKI, there are only a few single-center studies on which to establish recommendations. Patients who were on dialysis for less than 8 weeks should be listed for LTA based on (i) the absence of an established survival benefit for SLK in patients before 8 weeks; and (ii) data from University of California at Los Angeles (UCLA) indicating that over 90% of patients dialyzed for HRS for less than or equal to 4 weeks will recover renal function after LTA.

Even with this approach careful, ongoing assessment of patients for reversibility of AKI should be confirmed.

(iii) Retransplantation as a consideration in SLK

Two retransplant patient subgroups were identified. For patients in whom regrafting was indicated immediately after the primary transplant (e.g. primary non-function), SLK was not warranted as any insult to the kidneys above that present at the time of the initial transplant represented AKI. Patients being evaluated for retransplantation beyond 6 months posttransplant should be evaluated as all other patients generally are, described in subsection (ii) above. However, given the inferior results associated with retransplantation, greater care should be taken in evaluating these patients.

Net Benefit

There was significant discussion of net benefit and the ethical considerations of SLK with regard to taking potential

kidneys from ESRD patients. This discussion focused on the number of liver candidate lives being saved versus the number of kidneys being removed from the kidney pool to accomplish this. The point was made that relatively few additional lives of SLK recipients were being saved over those who received LTA. However, the number of these patients who would have subsequently required kidney after liver transplantation and thus received net benefit of kidney transplantation is unknown. This issue also must be considered along with the observation that the incidence of acute rejection and long-term kidney graft loss secondary to chronic rejection is greater in kidney after liver (KAL) transplantation than in the SLK kidney (21). Since organ shortage has fuelled proposals aimed at changing national kidney allocation policy to one of optimizing outcomes for donor organs, this issue has enormous implications. It was additionally recognized with regard to kidney alone candidates (i) 6% die each year on the waiting list, (ii) transplantation significantly extends life expectancy and (iii) increasing duration of dialysis reduces life expectancy. These issues accentuate the need for accurate determination of appropriate candidates for SLK.

Summary and Recommendations

The conference highlighted the increasing number of SLK transplants being performed and the recognition that there are different groups of patients based on CKD versus AKI, and ESRD patients with cirrhosis.

The most recent SRTR data shows a survival benefit at three years for SLK patients over LTA with a pretransplant serum creatinine greater than 2.0 mg/dL on dialysis. There is also benefit to the SLK group not on dialysis but only at one and two years posttransplant. This survival advantage is approximately 10%, although it requires around 400 kidneys from the donor pool to achieve this advantage. This fact must be considered in conjunction with the death rate of ESRD patients awaiting KTA when deciding whether or not to perform SLK versus LTA. Agreement was expressed that patients with ESRD and cirrhosis with documented portal hypertension should be candidates for SLK. Patients with stage IV or V CKD and ESLD should also receive SLK. In single center studies, patients with AKI secondary to HRS seem to have a survival advantage with SLK when pretransplant dialysis duration is eight weeks or more. The attendees at this conference agreed on the premise that certain parameters should warrant automatic approval for listing for SLK, while SLK listing of patients outside of these parameters should require approval of the Regional Review Board (RRB).

Automatic exception would be given to:

(i) ESRD patients with cirrhosis and symptomatic portal hypertension or hepatic vein wedge pressure with gradient greater than 10 mm Hg;

(ii) patients with ESLD and chronic kidney disease with GFR $\leq$ 30 mL/min;
(iii) patients with AKI including HRS with creatinine $\geq$ 2.0 mg/dL and dialysis $\geq$ 8 weeks; and
(iv) patients with ESLD and evidence of CKD and kidney biopsy demonstrating > 30% glomerulosclerosis or 30% fibrosis.

Other criteria to be considered in granting exceptions are the presence of comorbidities such as diabetes, hypertension or other preexisting renal disease, along with proteinuria, renal size and duration of elevated serum creatinine $\geq$ 2.0. Net benefit should also be considered when evaluating patients over age 65.

The final charge of the conferees was to establish a data registry to evaluate factors in determining the necessity of SLK. This web-based registry is now established and funded. All transplant centers are encouraged to participate in enrolling SLK patients as well as patients with CKD or AKI undergoing LTA.

The registry data elements were defined at the conference. Details of the registry can be obtained by contacting Dr. Gonwa at: Gonwa.thomas@mayo.edu.

Acknowledgments

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Appendix:

ASTS/AST

Combined Kidney/Liver Transplant Consensus Conference
September 10–11, 2007

Speakers:

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