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Simultaneous Liver-Kidney Transplantation: What are Our Obligations to the Kidney Only Recipient?

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Abstract
Purpose of Review There has been a recent explosion in the number of simultaneous liver and kidney (SLK) transplants performed. This practice is crowding out the population of ESRD patients waiting for a kidney transplant.
Recent Findings It has been alleged from retrospective, anecdotal reports, often from voluntary registries, that there is a survival advantage for those with renal dysfunction that receive an SLK compared to Liver Transplant Alone. However, this survival advantage is quite small—about 5% at 1 and 5 years at best. A new algorithm introduced in 2016 by UNOS may make this problem worse by allowing SLK transplant for patients who may not have permanent kidney failure with a glomerular filtration rate (GFR) as high as 30cm^3/min.
Summary The transplant community needs to have a high degree of vigilance to identify which groups of patients are being disadvantaged when reallocation schemes are created to direct organs from one group to another.

Keywords Simultaneous liver kidney transplant · Glomerular filtration rate · Organ allocation

Introduction

The Transplantation of solid organs to replace those that have lost function has evolved over the last 60 years from a high risk and rare endeavor, to a common, organized, and regulated clinical practice around the world. The early cases were exclusively done for kidney failure, but with the greater understanding of the alloimmune response, histocompatibility, the development of more selective and targeted immunosuppression, advances in surgical techniques and organ preservation; hearts, lungs, livers, pancreata, and bowel, can now be safely transplanted to those in need. Not surprisingly, patients have also emerged with failure of two or more solid organs at the same time. Various combinations of solid organs such as the heart and lung, heart and liver, liver and bowel, bowel and pancreas, and kidney and pancreas, from the same deceased donor can be transplanted together with lifesaving results. However, the greatest number of patients waiting for a solid organ and the greatest number of transplants performed worldwide remain the kidney.

In addition to primary etiologies of kidney failure such as hypertension, diabetes, glomerulonephritis, congenital diseases, genetic diseases (polycystic kidney disease), etc., kidney failure is now observed in a subset of patients with failure of another solid organ [1•]. Accompanying kidney failure can be observed at the same time of first organ failure such as those in severe heart failure with low cardiac outputs or after cardiac arrest. Accompanying kidney failure can also be observed later in the course of a well-functioning first organ due to sepsis or the cumulative use of nephrotoxic drugs (including the calcineurin inhibitors needed for transplant immunosuppression). In such cases, a deceased donor or living donor kidney transplant can be performed in a patient with a well-functioning non-renal organ. Such patients are treated the same as any other patient with ESRD after placement on the kidney transplant wait list. The limited supply of donor kidneys for transplant compared to the burgeoning demand for kidneys has created the need for wait lists and distribution criteria that continually adapt according to nationally mandated and regulated rules. It is also an established practice that

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uremic diabetics are eligible to receive both a kidney and a pancreas from the same donor when poorly controlled diabetes is present.

However, a new class of patient has emerged that is crowding out the population of ESRD patients waiting for a kidney transplant according to the current established criteria, namely those patients with end stage liver disease (ESLD) with accompanying acute or chronic kidney disease. No doubt kidney dysfunction is common among patients with ESLD, and may also progress in recipients with some degree of chronic kidney disease (CKD) that receive a liver transplant alone (LTA) [2–4]. One of the driving factors for the explosion in the number of SLK transplants has been the model for end stage liver disease (MELD) score introduced in 2002 as the algorithm for liver distribution by UNOS [5•]. Serum creatinine (surrogate for glomerular filtration rate (GFR)) is prominently featured in the MELD formula [6]. The goal of this report will be to review the impact of SLK transplantation today with particular emphasis on those waiting for a kidney.

Who Gets a Kidney?

In the USA, patients with confirmed ESRD and a GFR <20 cm^3/min become eligible for a kidney transplant if accepted by an active UNOS approved Transplant Center [7]. They may receive a kidney from a living donor or be placed on the deceased donor wait list according to the contemporary UNOS eligibility and allocation rules. If already on chronic dialysis, they remain on this modality; or they prepare for dialysis, usually when uremic symptoms occur and the GFR falls below 10cm^3/min. The time for the GFR to fall from 20 to 10 cm^3/min varies in each circumstance, but allows for the orderly evaluation of a potential kidney transplant candidate and/or preparation for dialysis. Many would like to be transplanted before the actual need for dialysis and surgery for vascular access, but this is not universally possible due to the frequently encountered wait time of at least 2–5 years (based on ABO blood group, histocompatibility, and degree of HLA sensitization). Those fortunate to have a living kidney donor proceed to transplant as clinical circumstances allow. Using this practice in the USA about 100,000 candidates are waiting for a kidney and about 19,000 (DD and LD) were transplanted in 2016 [8]. About 5% of wait list candidates for a kidney-alone die untransplanted each year; the largest group are those >60 years of age. Cardiovascular comorbidity is the leading cause of kidney wait list mortality. The mortality figures may actually be higher than reported as progressively ill candidates may be removed from the wait list before they actually expire [9].

Why and How Many SLK Transplants are Done?

Since 2001, the number of patients receiving an SLK transplant has exploded with >730 done in 2016. A 440% growth rate since 2001 (Fig. 1). It has been alleged from retrospective, anecdotal reports, primarily from reviews of incomplete voluntary registries, that there is a survival advantage for those with renal dysfunction that receive an SLK compared to LTA. However, this survival advantage is quite small—about 5% at 1 and 5 years [10•, 11] at best. Since no randomized controlled trials exist, there is no high quality evidence to confirm or refute this practice, and conclusions often depend on interpretations of incomplete data. Recent internal reviews by UNOS of national data do not display a survival advantage for SLK for recipients with liver failure and a SCr >2.5 mg/dL compared to LTA [Fig. 2].

A major subjective argument is that the simultaneous transplant of the kidney will overcome the need for dialysis in the early post liver transplant period. While theoretically true, as many as 50% of SLK recipients need further dialysis for a few weeks post-transplant due to ischemic injury to the allograft kidney. This can occur since the organ donors may be hemodynamically unstable, or the transplanted kidneys sustain further ischemic injury during liver transplant surgery. There are many reasons for this including the intense nature of the combined organ transplant, often accompanied by large blood loss, hypotension, major fluid shifts, poor cardiac performance, and extended anesthesia. However, contemporary dialysis practice in the ICU setting of a liver transplant center has advanced quite significantly during the past two decades. The use of CRRT by skilled nephrologists is commonly employed in ICUs to control AKI from many causes [12]. In fact, it may stabilize and control the volume status of critically ill patients far better than dependence on an ischemically damaged allograft kidney in the recovery phase from acute tubular necrosis.

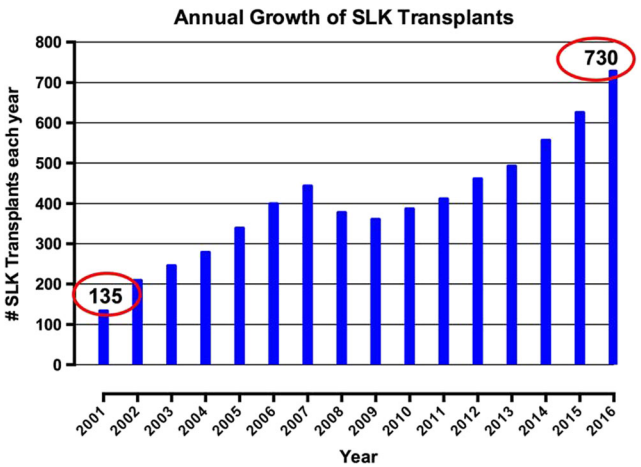
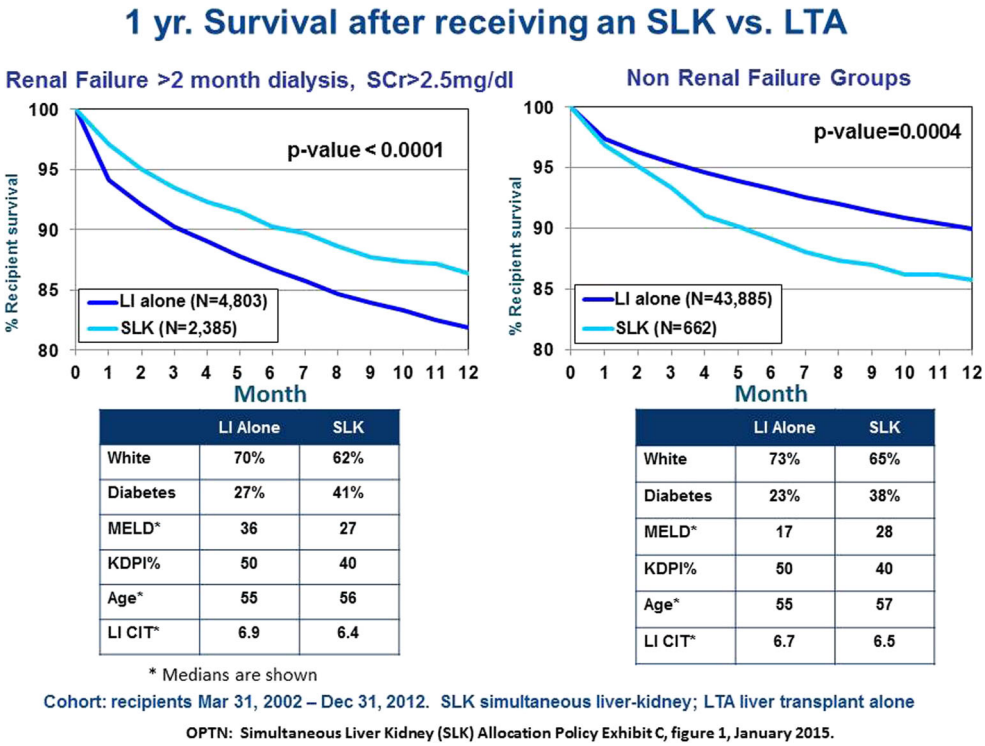


Fig. 1 Annual growth rate of simultaneous liver-kidney transplantation in the United Sates since 2001



	LI Alone	SLK
White	70%	62%
Diabetes	27%	41%
MELD*	36	27
KDPI%	50	40
Age*	55	56
LI CIT*	6.9	6.4

	LI Alone	SLK
White	73%	65%
Diabetes	23%	38%
MELD*	17	28
KDPI%	50	40
Age*	55	57
LI CIT*	6.7	6.5

Fig. 2 1-year survival after liver transplant alone or after simultaneous liver-kidney transplantation for those patients with (serum creatinine >2.5 mg/dL) or without renal failure

The New UNOS Algorithm

After several rounds of review and negotiation the UNOS SLK Committee addressed for the first time in 2016 written criteria for eligibility for an SLK transplant for those end stage liver disease (ESLD) patients with CKD, AKI, and metabolic diseases (Table 1) [10•]. An important caveat is that categories of acceptable kidney dysfunction must be confirmed by a nephrologist. For the CKD category patients must have a GFR ≤ 60 cm^3/min for 90 consecutive days and an estimated glomerular filtration rate (eGFR) or creatinine clearance (Clcreat) <30cm^3/min at registration or be on dialysis. For those with AKI, notably those with hepatorenal syndrome, they require continuous dialysis or an eGFR or Clcreat ≤25cm^3/min for 6 weeks, or a combination of these parameters during six consecutive weeks. The listed metabolic diseases are well known to cause permanent renal disease and are not controversial.

Table 1 Medical eligibility criteria for simultaneous liver-kidney transplantation. The following to be confirmed by a nephrologist

Chronic kidney disease
GFR ≤60 for 90 consecutive days and
eGFR or CrCl ≤30 at or after registration on kidney waiting list or
Dialysis (in the setting of ESRD)
Acute kidney injury
Dialysis for 6 consecutive weeks
eGFR or CrCl ≤25 for 6 consecutive weeks
Combination of above two criteria
Metabolic disease
Atypical Hemolytic Uremic Syndrome from mutations factor H or factor I
Hyperoxaluria
Familial non–neuropathic systemic amyloidosis
Methylmalonic aciduria

A new wrinkle in the algorithm, never introduced for other categories of organ failure, is the creation of a safety net for post LTA recipients with documented renal injury before the transplant that will be eligible to receive a fast tracked deceased donor kidney between 60 and 365 days after the LTA. The listed criteria are a GFR <20cm^3/min or the introduction of chronic dialysis. These are essentially the same criteria that all other ESRD patients are subjected to in current kidney allocation policies. However, in order to be fast tracked, some restrictions were placed such as limiting deceased donor organ quality (KDPI <35%) and distribution behind children and highly HLA sensitized candidates [10•].

Lastly, an important mandate was introduced that the host Organ Procurement Organization must share the kidney with the liver when the liver was to be exported out of the host donor service area. Justification for the safety net cited by the Committee was a review of internal data over a 10-year interval showing that patient survival in LTA patients was not affected if they were on the wait list and received a kidney within 1 year, but was diminished if they were on the waiting list 3 years or longer [10•].

Why is There Controversy?

There are no doubt that individuals with ESRD from independent etiologies also develop liver failure. Those with longstanding diabetes and/or severe hypertension, glomerulopathies, congenital or metabolic diseases, etc., may be already need dialysis or be near to dialysis at the time that liver failure becomes evident. A combined organ transplant may be best for such patients, and they are not part of the controversy.

A major concern is the arbitrary cut off of a GFR 30cm^3/min granting eligibility for SLK; some have pushed for criteria of GFR 35–40 cm^3/min. There are no other candidates for kidney transplant that become eligible with this level of renal function including prior kidney donors, children, or the hyperimmunized patients who require a GFR of 20cm^3/min. This criterion is not based on any high quality evidence and appears to be unfair, especially if it is used as a one-time threshold laboratory value. Even if an LTA recipient with a GFR of 30cm^3/min lost 10–40% of their residual kidney function, they would be very unlikely to need dialysis. Today, the number of patients with LTA who need dialysis after surgery remains low at <10% the first year. This is particularly true for patients with low GFR not accompanied by proteinuria [13•, 14]. Israni et al. reported characteristics that supported the suitability for LTA including non dialysis, absence of proteinuria, and relatively normal kidney biopsy and ultrasound findings (size) [13•]. This additional clinical information should be required before determining that an SLK is indicated for patients with low GFR ranges. Israni et al. have also developed a risk prediction tool to predict ESRD after LTA that include variables such as recipient age, gender, race, BMI, serum creatinine, albumin, and bilirubin, diabetes, positive hepatitis C serology, prior dialysis, cancer, liver donor risk index, and age. They reported good calibration and discrimination (C-statistics 0.74–0.78) using these equations in the 63,000 patients included in the final model. Overall, the authors found a low incidence of ESRD in the LTA patients below during the first 6 months (<5.3%), and (<10.7%) between 6 months and 5 years [13•].

When UNOS reviewed their own data patients with LTA that had no dialysis need or temporary dialysis need went on to ESRD in only 4–6% of cases during the first year [Fig. 3]. It is important to acknowledge that GFR estimations are less accurate in patients with ESLD, as commonly used creatinine-based calculation methods may lead to an overestimation of GFR [15]. This can be due to volume expansion, muscle wasting, and severe malnutrition leading to lower creatinine formation in some ESLD patients [16]. To confuse matters, some have found that eGFR equations may also underestimate true GFR in a subgroup of patients with >30 ml/min/1.73 m^2 [17, 18]. One can make the same clinical observations in an elderly, poorly nourished, 50 kg female with ESRD that has a lower actual GFR than the serum creatinine would indicate. The use of alternative endogenous biomarkers for GFR estimation, such as Cystatin C, may improve GFR measurements and limit the degree of overestimation [19, 20•].

Another major concern with the new policy involves the eligibility criteria for receiving SLK in patients with AKI and/or hepatorenal syndrome. The defining cut off of intermittent dialysis or GFR ≤25 for 6 weeks is arbitrary and shortens the duration from a prior loose consideration of 4–8 weeks of intermittent dialysis. Since most patients with ESRD do not dialyze until the GFR is <10cm^3/min, substituting a GFR ≤25 is open for abuse. In addition, the recovery from AKI in ESLD patients after LTA may be difficult to predict, but it certainly occurs and may be best predicted for those with maintained normal sized kidneys and no other nephrotoxic comorbidities. As an example, using radionuclide scans, it was estimated that at least a third of such patients were found to have recovered native kidney GFR >20cm^3/min when they met UNOS criteria for an SLK [21•]. It seems much more prudent to have more restrictive criteria to avoid unnecessary kidney transplants in a substantial number of patients (thereby denying others a life-saving organ), than to miss a few who cannot survive without post liver transplant dialysis. The latter, of course, will benefit from the newly created safety net for more rapid acquisition of a kidney after LTA.

Unintended Consequences

There are a number of unintended consequences that spin off from doing increasing numbers of SLK transplants at the expense of kidney transplant alone in ESRD patients. These are difficult to debate and do create champions and detractors around each issue. As an example, the rapid expansion of SLK transplantation directly causes a reduction in live donor kidney transplantation. Why? When appropriate candidates for SLK are identified, they have high MELD scores and are fast tracked to receive both organs. These patients and families are told of shortened wait times, and the possibility to receive a live donor kidney from a family member or friend is foreclosed. This is especially troubling for those patients not on chronic dialysis with a GFR >20cm^3/min. Such patients could receive an LTA, followed a few months later by a live donor kidney after they had sufficiently recovered from the LTA. In fact, this is the principle of the safety net, and is commonly done today in other solid organ transplant recipients that develop ESRD months or years after the first organ is transplanted. Therefore, the current practice of universal deceased donor SLK may remove a potential live donor kidney from the overall donor pool and remove one from those waiting for a deceased donor kidney-alone.

Another concern of the new policy revolves around the diminished survival of the kidney in an SLK recipient compared to a kidney-alone candidate. The excess loss rate

Prior Liver-Alone Recipients (January 2005 – June 2015) by SLK Medical Eligibility Criteria and whether they Developed ESRD within a Year of the Transplant

Would Liver Alone recipient have met proposed SLK Eligibility Criteria?		ESRD Within 1 Year of Liver Transplant				Total	
		Went on to have ESRD		Did not go on to have ESRD			
		N	%	N	%	N	%
Chronic Kidney Disease	On Dialysis for ESRD at Time of Transplant	NA	NA	NA	NA	20	0.0
	Not on Dialysis for ESRD, eGFR <21	306	9.8	2,812	90.2	3,118	6.4
	Not on Dialysis for ESRD, eGFR 21-25	98	6.6	1,397	93.4	1,495	3.1
	Not on Dialysis for ESRD, eGFR 26-30	105	6.3	1,563	93.7	1,668	3.4
Sustained acute kidney injury	On dialysis for 6+ weeks before transplant	12	6.6	170	93.4	182	0.4
Would not qualify for SLK	No Dialysis for ESRD or Temporary dialysis for 6+ weeks, eGFR 31-35	61	3.6	1,616	96.4	1,677	3.5
	No Dialysis for ESRD or Temporary dialysis for 6+ weeks, eGFR >35	633	1.6	39,730	98.4	40,363	83.2
Total		1,215	2.5	47,308	97.6	48,523	100.0

Fig. 3 Prior liver-alone transplant recipients (January 2005–June 2015) by new allocation medical eligibility criteria and whether they developed ESRD within a year of the transplant

approaches 5–7% for the first year. Since longevity matching of kidneys was an overriding concern of UNOS when the recent Kidney Allocation (KAS) algorithm was introduced in December 2014, it is difficult to reconcile this glaring inconsistency in optimizing kidney survival [22]. This is especially troubling since the transplant community has not come to grips with controlling the number of futile SLK transplants that are still performed, which are a direct cause of early kidney loss [23•, 24•]. Very often, the unregulated and unmonitored practice of SLK can be used to offload accountable programmatic risk when extremely ill and marginal candidates receive a liver transplant. Again, one can appreciate the need for SLK transplants in patients with permanent failure of both organs, but these unintended consequences of SLK do not generate enthusiasm for the practice in those patients not on permanent dialysis and with a substantial opportunity for native kidney recovery.

Conclusions

It is inevitable that a consistently growing use of deceased donor kidneys for SLK transplantation harms those waiting for a kidney-alone. Indeed, a stated purpose of the new UNOS algorithm was to restrict SLK to those with defined and consistent medical criteria for eligibility. This is the unfortunate consequence of a donor supply that is outstripped by a greater need for transplantable organs. The survival advantage for SLK compared to LTA seems a reasonable goal for those with permanent failure of both organs. One may also posit that combined organ failure candidates are sicker and in greater need of organs, especially those that are lifesaving of themselves (heart, lung, liver). However, the transplant community needs to have a high degree of vigilance to identify which groups of patients are being disadvantaged when reallocation schemes are created to direct organs from one group to another. It is difficult to support doing SLK transplants for those patients with a GFR > 20 cm^3/min or for those with potentially recoverable AKI. Frankly, any supposed survival advantage for SLK is outweighed, if not trumped, by the excess wait list mortality for kidney-alone patients.

The introduction of a safety net for those LTA patients with the developing need for permanent renal replacement therapy, the first year should protect those with inadequate native renal function. Encouraging live donor kidney transplant for LTA patients with ESRD should also be prioritized after a reasonable period of recovery. There is no justification to use a kidney allograft in a candidate with sufficient native renal function to stay off dialysis, or for those with recoverable native kidney function after ESLD is reversed.

To summarize, the exploding numbers of SLK transplants have rapidly come upon the transplant community with little oversight and reasoned analysis for balancing need and fairness. It is essential that ongoing review of organ distribution and transplant outcomes are transparent and align with the new criteria set down by UNOS. Further modifications should

be rapidly introduced should the numbers of SLK cases continue to expand at the current unsustainable rates.

CKD, chronic kidney disease; CLcreat, creatinine clearance; CRRT, continuous renal replacement therapy; ESRD, end stage renal disease; ESLD, end stage liver disease; eGFR, estimated glomerular filtration rate; GFR, glomerular filtration rate; ICU, intensive care unit; KDPI, kidney donor profile index; LTA, liver transplant alone; MELD, model for end stage liver disease; SLK, simultaneous liver kidney transplant

Compliance with Ethical Standards

Conflict of Interest Stuart Flechner reports grants from Novartis Pharma outside the submitted work.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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