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# The Survival Benefit of Deceased Donor Liver Transplantation as a Function of Candidate Disease Severity and Donor Quality

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**The survival benefit of liver transplantation depends on candidate disease severity, as measured by MELD score. However, donor liver quality may also affect survival benefit. Using US data from the SRTR on 28165 adult liver transplant candidates wait-listed between 2001 and 2005, we estimated survival benefit according to cross-classifications of candidate MELD score and deceased donor risk index (DRI) using sequential stratification. Covariate-adjusted hazard ratios (HR) were calculated for each liver transplant recipient at a given MELD with an organ of a given DRI, comparing posttransplant mortality to continued wait-listing with possible later transplantation using a lower-DRI organ. High-DRI organs were more often transplanted into lower-MELD recipients and vice versa. Compared to waiting for a lower-DRI organ, the lowest-MELD category recipients (MELD 6–8) who received high-DRI organs experienced significantly higher mortality (HR $=$ 3.70; $p < 0.0005$). All recipients with MELD $\geq$20 had a significant survival benefit from transplantation, regardless of DRI. Transplantation of high-DRI organs is effective for high but not low-MELD candidates. Pairing of high-DRI livers with lower-MELD candidates fails to maximize survival benefit and may deny lifesaving organs to high-MELD candidates who are at high risk of death without transplantation.**

**Key words: Donor risk, liver transplantation, MELD score, SRTR, survival benefit**

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## Introduction

Liver transplantation is the primary therapy for patients with end-stage liver disease. Unfortunately, the gap between the number of patients on the liver transplant waiting list and the number of patients transplanted remains wide, and more than 2000 candidates die each year while awaiting transplantation (1). The scarcity of deceased donor livers highlights the need to allocate available organs such that the benefit to the patient population is maximized. Currently, candidates on the deceased donor liver transplant waiting list are prioritized by medical urgency (i.e. risk of waiting list death). Specifically, after allocation to candidates with fulminant hepatic failure, which is fatal within days, the waiting list is sequenced by decreasing model for end-stage liver disease (MELD) score, a very strong predictor of waiting list mortality (2–4).

An attractive alternative to the current urgency-based system is allocation based on survival benefit (i.e. the contrast between posttransplant and waiting list mortality). There are several useful ways to characterize the survival benefit associated with liver transplantation. One method calculates the covariate-adjusted ratio of post- to pretransplant mortality rates, and is the direct output of a standard Cox regression model.

Using such a model and with a maximum of 1 year of posttransplant follow-up, transplant recipients with a MELD score $\geq$17 derived significant survival benefit, including patients at the maximum MELD score of 40 (5). In contrast, patients at low MELD scores faced much lower mortality risk on the waiting list and hence did not derive a survival benefit from liver transplantation.

Notwithstanding its valuable contribution to the understanding of liver transplant survival benefit, the preceding work had at least three important limitations. First and foremost, the impact of donor quality on posttransplant mortality risk was not considered, even though it would considerably affect posttransplant survival and hence transplant benefit. Second, the analysis was based on a maximum of 1 year of posttransplant follow-up. Including additional posttransplant follow-up would increase the estimated survival benefit, since follow-up time would increasingly distribute away from the high-risk perioperative

period. Third, the MELD-subgroup-specific survival benefit estimates pertained to a patient's then-current MELD and did not account for future MELD changes, leading to limited interpretation. For example, for a patient with a MELD of 10, the pertinent benefit estimate derived from Merion et al. would apply only while the patient remained at a MELD of 10 and would change if and when the patient's MELD score changed (5).

The primary objective of the current investigation was to estimate the survival benefit of liver transplantation by cross-classifications defined by MELD and a recently developed liver donor risk index (DRI) (6). The DRI is a continuous measure that reflects the risk of graft failure (including death); a higher DRI is associated with a greater risk of graft failure. Specifically, we sought to address the following question: should a patient with a given MELD score undergo transplantation when the deceased donor liver being offered has a particular DRI; or remain on the waiting list, risking the possibility of death or further clinical deterioration, for the future possibility of being offered an organ with a lower risk of failure? To answer this question, we utilized national data that include up to 3 years of posttransplant follow-up and employed a recently developed analytic method that accounts for future MELD score changes in calculating estimates of liver transplant survival benefit.

## Methods

Data were obtained from the Scientific Registry of Transplant Recipients (SRTR) and based on patient-level data submitted by transplant centers to the Organ Procurement and Transplantation Network (OPTN). The study population (n = 26 165) consisted of candidates initially wait-listed at age ≥18 between September 2001 and July 2005. Each was observed until the earliest of death, living donor liver transplantation, the granting of an exception MELD score by a regional review board (i.e. not based on the underlying laboratory values) or loss to follow-up.

For each deceased donor liver transplant, DRI was computed for the transplanted organ as defined by Feng et al. (6). Transplanted livers were grouped into one of three DRI categories: low (lowest quartile of DRI distribution; $0 < \text{DRI} \leq 1.075$), medium (middle two quartiles; $1.075 < \text{DRI} \leq 1.65$) and high (highest quartile; $\text{DRI} > 1.65$).

The analysis was based on sequential stratification (7), an extension of Cox regression for evaluating time-dependent treatments (e.g. transplantation) in the presence of time-dependent patient characteristics (e.g. MELD). A separate stratum was created whenever a deceased donor liver transplant occurred at a unique number of days since wait-listing. Each stratum included the transplanted patient and a matched set of 'control' patients who, at the same number of days since initial wait-listing, were active on the waiting list, had the same MELD score as the index patient at the time of transplant, were in the same age group (18–39, 40–49, 50–59, 60–69, ≥70) and were wait-listed in the same OPTN region as the index-transplanted patient. Once included in a stratum, matched controls were not censored by any of the following subsequent events: MELD score changes, removal from the waiting list, or subsequent receipt of a transplant with a DRI lower than that of the transplant to which they were matched. Control patients were censored from a stratum only if they received a transplant with a DRI greater than that of the index transplant.

Strata were combined and Cox regression was used to estimate covariate-adjusted MELD×DRI subgroup-specific hazard ratios (HRs). Covariates in the Cox model included recipient gender, race, diagnosis, albumin, body mass index, diabetes mellitus, dialysis dependence, medical condition at listing (not hospitalized, hospitalized in an intensive care unit or hospitalized outside an intensive care unit) and MELD score trajectory (slope of the regression line based on all previous MELD scores). Age, MELD and OPTN region, being matching criteria, were adjusted through stratification. As a subanalysis, we combined across all DRI categories and estimated HRs by MELD category.

The analysis was designed specifically to estimate the survival benefit associated with deceased donor liver transplantation for a patient at a given MELD score using a liver with a specific DRI. The natural comparison group is not candidates who remained wait-listed per se, but rather candidates who waited for a transplant with a lower DRI organ. Not censoring the matched controls if, after entering a stratum, they subsequently received an organ with a lower DRI, permitted estimation of HRs with the desired interpretation. This survival analysis method was an extension of that proposed by Schaubel, Wolfe and Port to evaluate the survival benefit of expanded criteria donor kidney transplantation (7).

As a subanalysis, we repeated the above-described analysis using donor age to measure graft failure risk, rather than the DRI score itself. Donor age is one of the strongest and most variable graft failure risk factors. Other strong risk factors include donation after cardiac death (DCD) and use of a partial or split liver. However, the low prevalence of DCD and partial/split livers made analysis by these DRI components unfeasible.

All statistical analyses were conducted using SAS v9.1.3 (SAS Institute, Cary, NC).

## Results

Characteristics of the study population are presented in Table 1. At the time of initial wait-listing, the mean MELD score was 16 and the mean age was 53 years. Approximately 35% of patients were female and 27% were racial/ethnic minorities.

Median DRI tended to decrease as MELD at transplant increased (Figure 1). The highest median DRI (1.50) was observed among patients transplanted while in the lowest MELD categories (6–8 and 9–11). Median DRI was 1.22 for patients transplanted with a MELD of 40.

Figure 2 contains four sets of covariate-adjusted HRs and 95% confidence intervals (CI) plotted on the $\log_{10}$ scale for low DRI (Figure 2A), medium DRI (Figure 2B) and high DRI (Figure 2C ); Figure 2D is based on all liver transplants. Patients with MELD 6–8 who received a high-DRI liver transplant experienced mortality rates more than 3.5 times as high as candidates who remained on the waiting list and possibly later received a lower-DRI organ ($\text{HR} = 3.70$; $p < 0.0005$) (Figure 2A). Similarly, patients in the MELD 9–11 category experienced a significant 1.8-fold higher

**Table 1:** Characteristics of study population (n = 28 165) at initial wait-listing

| Candidate characteristic | Percentage of study population or mean (min, max) |
|---|---|
| MELD | 16.0 (6, 40) |
| Albumin | 3.0 (0.5, 9.9) |
| Age | 52.5 (18, 83) |
| Female | 35.0% |
| Race | |
| African American | 7.6% |
| Asian | 3.9% |
| Hispanic/Latino | 14.2% |
| White | 73.2% |
| Other race | 1.1% |
| Diagnosis | |
| Acute hepatic necrosis | 1.8% |
| Cholestatic cirrhosis | 8.6% |
| Hepatitis C | 42.0 |
| Malignant neoplasm | 2.1% |
| Metabolic disease | 1.7% |
| Noncholestatic cirrhosis | 34.3% |
| Other diagnosis | 9.3% |
| Body mass index | 28.5 (17.7, 45.5) |
| Diabetes | 21.0% |
| Dialysis-dependent | 3.1% |
| Hospitalization status | |
| Not hospitalized | 87.7% |
| Hospitalized in intensive care unit | 3.9% |
| Hospitalized, not in intensive care unit | 8.4% |

mortality risk relative to patients who waited for and possibly received a liver transplant with a lower-DRI organ (HR = 1.79; $p < 0.005$). In contrast, patients with MELD scores ≥20 who were transplanted with a high-DRI liver demonstrated a significant survival benefit (i.e. reduction in mortality rate). For example, patients with a MELD of 40 transplanted with a high-DRI organ experienced 69% lower mortality than comparable wait-listed candidates who continued to wait for a lower-DRI liver (HR = 0.31; $p < 0.0005$).

Corresponding results are displayed in Figure 2B for transplantation with medium DRI livers. Patients with MELD 9–11 experienced a borderline-significant 46% higher mortality upon accepting a medium DRI organ (HR = 1.46; $p = 0.064$) relative to waiting for a lower-DRI organ. Patients in no other MELD category experienced a significant mortality increase by accepting a medium DRI organ, although the lack of significance in the MELD 6–8 category needs to be interpreted with caution since the HR of 1.84, while not statistically significant ($p = 0.096$), represents the outcomes from a relatively small number of transplants in this cell. Patients with MELD scores ≥15 had a significantly lower mortality with transplantation with a medium DRI organ, and the magnitude of the survival benefit of a medium DRI liver increased monotonically with increasing MELD.

In Figure 2C, HRs for low-DRI liver transplantation are displayed. No MELD subgroup experienced significantly higher mortality with low-DRI liver transplantation compared to mortality on the waiting list. Patients with MELD scores ≥12 experienced a significant mortality risk reduction with a low-DRI transplant.

The HRs shown in Figure 2D represent all transplants in each MELD score category aggregated across all DRI levels. Recipients in the MELD 6–8 (HR = 2.38) and MELD 9–11 (HR = 1.50) categories experienced a significantly higher mortality risk with liver transplantation than comparable candidates on the waiting list (each $p < 0.0005$). For patients with MELD 12–14, transplant mortality rates were slightly and nonsignificantly decreased (HR = 0.86; $p = 0.15$). Patients with MELD scores ≥15 demonstrated

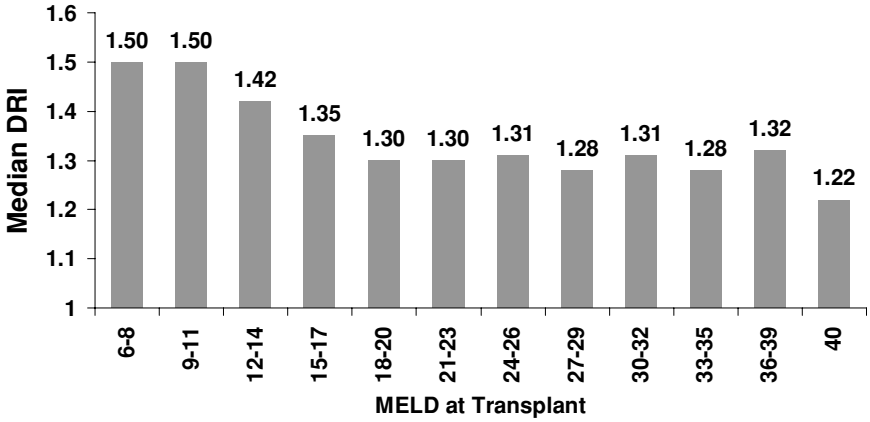


**Figure 1: Median donor risk index (DRI) by model for end-stage liver disease (MELD) score at transplant.** The DRI formula is given by: DRI = exp[(0.154×I(40≤ age <50) + 0.274×I(50≤ age <60) + 0.424×I(60≤ age <70) + 0.501×I(70≤ age) + 0.079×I(COD = anoxia) + 0.145×I(COD = cerebrovascular accident) + 0.184×I(COD = other) + 0.176×I(race = African-American) + 0.126×I(race = other) + 0.411×I(DCD) + 0.422×I(partial/split) + 0.066(170 − height)/10) + 0.105×I(regional share) + 0.244×I(national share) + 0.010×(cold ischemia time − 8 h)], where I(A) = 1 if A is true and 0 otherwise, COD = cause of death and DCD = donation after cardiac death (Feng et al., 2006).

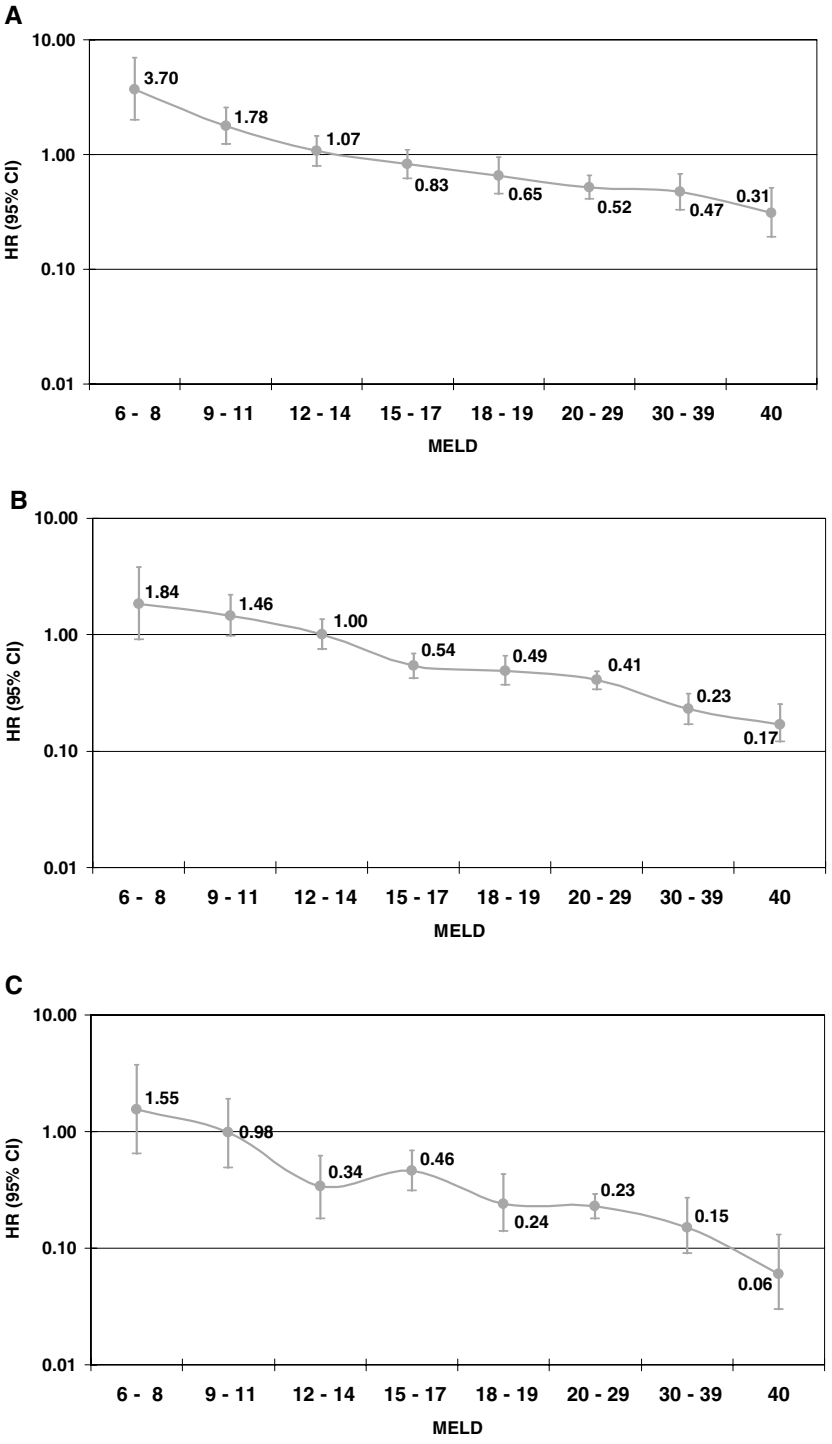


**Figure 2: Covariate-adjusted mortality hazard ratios (HR) and 95% confidence intervals (CI) by MELD score and DRI for (A) high DRI (upper quartile) deceased-donor liver transplants, (B) mid DRI (second and third quartiles), (C) low DRI (lower quartile) and (D) all DRI.** In each of the analyses, the comparison group comprises patients who remained on the waiting list and possibly later received a lower-DRI organ.

significant survival benefit from transplantation. The results in Figure 2D can be attributed largely to the waiting list mortality rate faced by patients, as well as the quality of organs received by patients upon liver transplantation (Figure 1). If practice patterns were to change such that higher-MELD patients were receiving higher-DRI organs (and lower-MELD patients were receiving lower-DRI organs), Figures 2A–2C, which are already DRI-specific, would likely remain unchanged, although the overall HRs (across all DRI) in Figure 2D would trend closer to HR = 1.00.

As a subanalysis, we replaced DRI with the DRI components in the MELD×DRI analysis. The strongest donor risk

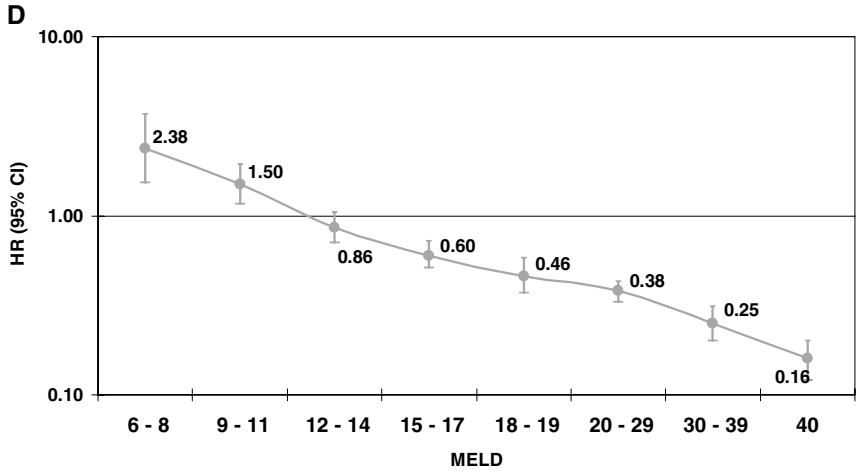


**Figure 2:** Continued.

factors for graft failure are donor age, DCD and partial/split liver, as evidenced by the DRI formula (Table 2, footnote). However, prevalence of DCD and partial/split liver was too low to make analysis feasible. As was the case for DRI, we subdivided the organs by donor age into 'low' (lowest quartile; age <25), 'medium' (middle two quartiles; age 25–54) and 'high' (upper quartile; age 55+). Patterns in the HRs by donor age group were generally similar to those for DRI (data not shown), although the dose-response relationship was stronger and more consistent for DRI. This is not surprising, since DRI considers many factors in addition to donor age and therefore should be a more accurate measure of graft failure risk than donor age alone. Note that donor age does not dominate the DRI, as the rank correlation between DRI and donor age was only 0.73, signifying that, although donor age is a strong risk factor for graft failure, the other DRI components contribute substantially.

**Table 2:** Distribution of transplants (n = 7873) by model for end-stage liver disease (MELD) score and donor risk index (DRI)

| MELD | N | High DRI row% | Mid DRI row% | Low DRI row% |
|---|---|---|---|---|
| 6–8 | 184 | 37 | 41 | 22 |
| 9–11 | 450 | 38 | 46 | 16 |
| 12–14 | 873 | 34 | 47 | 19 |
| 15–17 | 1305 | 28 | 50 | 22 |
| 18–19 | 762 | 23 | 50 | 27 |
| 20–29 | 2595 | 22 | 50 | 28 |
| 30–39 | 1211 | 19 | 54 | 27 |
| 40 | 493 | 17 | 54 | 29 |
| Total | 7873 | 25 | 50 | 26 |

Donor risk index = exp[(0.154×I(40≤ age <50) + 0.274×I(50≤ age <60) + 0.424×I(60≤ age <70) + 0.501×I(70 ≤ age) + 0.079×I(COD = anoxia) + 0.145×I(COD = cerebrovascular accident) + 0.184×I(COD = other) + 0.176×I(race = African-American) + 0.126×I(race = other) + 0.411×I(DCD) + 0.422×I(partial/split) + 0.066(170 − height)/10) + 0.105×I(regional share) + 0.244×I(national share) + 0.010×(cold ischemia time − 8 h)], where I(A) = 1 if A is true and 0 otherwise, COD = cause of death and DCD = donation after cardiac death (Feng et al., 2006).

## Discussion

Liver transplantation represents the outcome of a series of interrelated choices made by patients and caregivers. Historically, individuals with serious irreversible liver disease for whom no other therapies were available were referred for evaluation as liver transplant candidates. Over time, liver transplantation has become the preferred and definitive therapy for a wide variety of such diseases. Timing of liver transplantation is a more vexing problem, because the course of the underlying disease is not completely predictable in the absence of a transplant, and there is a need for a donor organ whose quality and time of arrival may be uncertain. It has been previously reported that among candidates whose risk of death without transplant is low, based principally on MELD score, there is a higher likelihood of death with a transplant than without one over a 1-year follow-up interval (5). The results of that study were based upon the conditional relative mortality risk with and without a transplant, within categories of MELD score. The characteristics of the donors were not considered in that study.

Conventional wisdom heretofore has suggested that donor livers at lower risk of failure (i.e. low DRI) should be directed towards patients at higher risk of waiting list mortality (i.e. high MELD), consistent with the theory that more frail patients should not be further challenged upon transplantation by receiving a high-risk organ. Conversely, there is a belief that healthier patients on the waiting list can tolerate the challenge of transplantation with a high-risk organ and still gain a survival benefit. Our findings reflect adherence to that conventional wisdom, showing that transplant surgeons have generally utilized donor livers with a lower risk of failure for candidates with higher MELD scores, and organs with a higher than average risk of failure for candidates with the least risk of death without transplant.

Unfortunately, conventional wisdom fails to focus on the most relevant issue, namely, the relative survival benefit

of receiving a transplant versus not receiving one. Naturally, any candidate would prefer a lower-risk organ to a higher-risk organ. But if an offer of a higher-risk organ is spurned, will that candidate live long enough to be offered a lower-risk liver later? Or will that candidate suffer further clinical deterioration that may harm his or her posttransplant outcome? Our analytic design directly addressed this question, and the results showed that high-MELD patients experienced significant survival benefit even when they received a high-DRI organ. On the other hand, patients with low MELD scores (and their correspondingly low waiting list mortality risk), whose survival benefit in general from liver transplantation is limited or even negative, had especially poor outcomes if they received a high-DRI organ. Our results suggest that the current informal practice of inverse matching of recipient MELD score and liver DRI (occurring, presumably, through turndowns of high-DRI liver offers for high-MELD candidates), should be discouraged.

When averaged across the entire DRI distribution and based on up to 3 years of posttransplant follow-up, we found that patients transplanted in the MELD 6–8 and MELD 9–11 categories experienced significantly higher mortality with transplant, as a function of their relatively low waiting list mortality rates and their greater propensity to receive higher-DRI livers. Overall, patients with MELD $\geq$17 experienced a significant mortality reduction via liver transplantation, a finding consistent with the results of Merion et al. (5), which were based on a maximum of only 1 year of posttransplant follow-up.

A previous study based on a Markov simulation (8) also considered whether liver transplant candidates should accept a higher-risk organ or wait for a lower-risk organ. Although that study reached conclusions similar to our own, the basis of its findings was considerably weaker (9). For example, the authors dichotomized livers as derived from expanded criteria or standard criteria donors. Moreover, the results were limited to 1-year patient survival. Most importantly, because the study used simulation and relied heavily on statistical models, the validity of their results rests heavily on unverifiable assumptions. The current study addresses all of these weaknesses by studying actual mortality experiences in a large national cohort of patients.

Our investigation shares the limitations typically associated with observational data. In studies where treatment is not randomly assigned, there is the potential for unmeasured patient characteristics to confound the results. This concern is greatest with respect to the MELD 6–8 patients, as it is possible that MELD and the set of patient characteristics included as model covariates do not fully describe their risk of death. The distributions of the adjustment covariates significantly predictive of mortality were quite comparable between low-MELD patients receiving high-DRI livers and low-MELD patients receiving medium- or low-DRI livers (data not shown). If anything, the overall case mix was slightly more favorable for recipients of low-/medium- (compared to high-) DRI livers. Given the observational nature of our data, we cannot rule out the possibility that, among patients transplanted at low MELD scores, the high-DRI liver recipients are less healthy in ways not captured by the SRTR database. However, in assessing the potential for such bias, it is important to note that our results are adjusted for what are likely the strongest mortality risk factors (e.g. MELD, albumin, age, diagnosis). To introduce bias, missing covariates would have to predict mortality strongly and be correlated with recipient DRI, after adjusting for all confounding factors currently in the model. Such bias, while possible, appears to be unlikely to have had a major effect on our findings.

Aside from the potential for missing important covariates, there are at least two other considerations in interpreting the lack of observed transplant survival benefit in low-MELD patients. First, we still have a relatively limited duration of posttransplant follow-up, so it is possible that survival benefit may yet be observed for low-MELD patients in the long run. For example, with 10 years of posttransplant follow-up, post- and perioperative mortality may play less of a role than in the current study, and hence overall posttransplant mortality may be lower than that on the waiting list. On the other hand, the impact of recurrent disease (e.g. hepatitis C, hepatocellular carcinoma), accelerated atherosclerosis and renal dysfunction from immunosuppressive drugs, and immunosuppression-related malignancy and opportunistic infection will all have disproportionately adverse effects on posttransplant mortality risk. Notwithstanding these considerations, increased follow-up is unlikely to change the ordering of the relative mortality risks for various combinations of MELD and DRI. Therefore, results based on longer follow-up are unlikely to contradict the recommendations made based on our current findings. Second, even with the currently available follow-up, low-MELD patients (e.g. MELD 9–11) have a HR not significantly different from 1.0 (implying equality of posttransplant and waiting list survival), even for low-DRI livers. Assuming that quality of life and the overall burden of disease are considerations in patient decision-making, such transplants could be considered beneficial (using the term more broadly to include not only patient survival).

Although our findings indicate that patients with MELD $\geq$20 experienced significantly lower mortality with transplantation, even when a high-DRI liver was used, we do not recommend, for example, that all candidates with high MELD scores should be transplanted. The observed data are a function of past practice patterns and any resulting selection bias. It is likely that clinician judgment goes into deciding which high MELD score patients will benefit from liver transplantation. However, we have shown that liver transplantation of high-MELD patients, as currently practiced, has been highly successful in saving lives, even when high-DRI livers are used.

Similarly, we do not suggest that all high-DRI organs should be utilized. Selection occurs in deciding which organs are transplanted versus discarded as well as in determining whether a given donor organ is accepted when offered for a specific candidate. Our results indicate that high-DRI transplants produce survival benefit in high-MELD patients. If one or both of the selection mechanisms were not operative, our results for high-MELD–high-DRI transplants might have been very different, but the magnitude of any difference in the results cannot be determined from the available data. In addition, despite the obvious utility of the DRI concept, it was developed using observational data (6). Organ or donor characteristics not available in the SRTR database may have affected whether or not particular deceased donor livers were utilized, and it is known that the percentage of recovered livers that are ultimately discarded increases with increasing DRI (6). Nevertheless, the high-DRI livers that were utilized did provide a survival benefit for candidates with MELD scores of 20 and higher. Therefore, one may surmise that at least some of the high-DRI organs currently being discarded or not recovered in the first place would provide lifesaving transplants for high-MELD candidates on the waiting list for liver transplantation.

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