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Patients' Willingness to Accept Expanded Criteria Donor Liver Transplantation

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Utilization of livers from expanded criteria donors (ECD) is one strategy to overcome the severe organ shortage. The decision to utilize an ECD liver is complex and fraught with uncertainty for both providers and patients. We assessed patients' willingness to accept ECD liver transplantation (LTx) and acceptable 1-year mortality risk. One hundred eight patients listed for LTx were asked to rate their willingness to accept ECD LTx and the associated 1-year mortality risk they were willing to accept. Also, patients completed the SF-36v2 and sociodemographic and health information was gathered from their medical records. Patients reported significantly higher willingness to accept standard criteria donor (SCD) versus ECD LTx ($t = 13.8$, $p < 0.001$), with more than one-third of patients reporting low willingness to accept ECD LTx. Relative to our center's 10% SCD LTx 1-year mortality rate, most patients (71%) were willing to accept moderately or substantially higher 1-year mortality risk for ECD LTx. In multivariable analyses, higher lab MELD score and white race were significant independent predictors of both ECD willingness and ECD increased mortality risk acceptability. Findings highlight the importance of assessing patients' willingness to pursue ECD LTx and the relative mortality risks they are willing to accept.

Key words: Expanded criteria donor, liver transplantation, quality of life

Abbreviations: BIDMC, Beth Israel Deaconess Medical Center; CIT, cold ischemic time; DCD, donation after circulatory death; DRI, donor risk index; ECD, expanded criteria donor; HCV, hepatitis C virus; LTx, liver transplantation; MELD, model for end-stage liver disease; CTP, Child–Turcotte–Pugh; QOL, quality of life; SRTR, Scientific Registry of Transplant Recipients.

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Introduction

Despite notable efforts to increase rates of deceased organ donation and living liver donation, the supply of livers has not kept pace with the growing demand for transplantation (1–5). Increased utilization of livers from higher risk deceased donors is one strategy to overcome the severe organ shortage, although there is no uniformly accepted definition for what constitutes an expanded criteria donor (ECD) liver (6,7). Some donor-related variables may increase risk for compromised graft and patient survival following LTx, including prolonged cold ischemic time (CIT), age, steatosis, partial graft, positive serologies for HBV/HCV/HTLV-1, female sex, high serum sodium ($Na + >155$), elevated transaminases, elevated bilirubin, prolonged down time and donation after circulatory death (DCD) (7–9). A donor risk index (DRI) with many of these individual components has been developed (9) and can be used to assess the relative risk for every potential graft and to determine the risk for a specific recipient. While all the components of the DRI are only available at the time of an organ offer, the individual components of the DRI are consistent with those that have been considered as risks for ECD grafts by most groups.

The decision to utilize an ECD liver for transplantation is complex and considers the patient's disease severity, comorbidities, survival without transplantation, expected graft and patient survival following transplantation and donor risk indicators. During the preliver transplant (LTx) period, patients are informed of ECD livers, their ECD LTx eligibility and the risks and benefits of ECD versus standard criteria donor (SCD) transplantation. While graft and patient survival data for ECD kidney transplantation are readily accessible (2), similar data for ECD LTx are not available. Importantly, patients must provide explicit consent for ECD LTx. This may be a challenging clinical decision-making process for some patients, who must balance the risks/benefits of an earlier ECD LTx with the risks/benefits of waiting for a SCD LTx, all at a time when physical, emotional and cognitive resources may be compromised.

While there is considerable discussion about the definition, breadth and outcomes of ECD LTx, there are no studies examining patients' willingness to accept ECD LTx. The aims of this study were to assess patients' willingness to accept ECD LTx, identify the increase in mortality risk they

are willing to assume relative to SCD LTx and examine the associations between sociodemographic variables and ECD LTx willingness.

Methods

Study design, setting and participants

Patients who were listed for LTx and attending an outpatient transplant clinic appointment were recruited from Beth Israel Deaconess Medical Center (BIDMC) in Boston, Massachusetts. Inclusion criteria were as follows: active on the LTx waiting list; transplant hepatologist or surgeon determined that the patient was medically eligible to receive ECD LTx and discussed this option with the patient; ability to read, speak and understand English; and ability to provide written informed consent. Exclusion criteria were: prior LTx; listed for combined liver-kidney transplantation; and acutely ill or unable to participate actively in the assessment (e.g. hepatic encephalopathy). Study procedures were approved by the BIDMC Institutional Review Board.

BIDMC adds 75–100 patients to the waiting list annually and performs 25–40 LTx per year. At study initiation there were 136 patients on the LTx waiting list. In the 3 years before the study, we performed 73 LTx (excluding retransplant and combined liver-kidney transplants)—49 SCD (67%) and 24 ECD (33%). We offer ECD LTx to all patients, except an HCV + organ into an HCV− recipient and a DCD organ into patients with portal vein thrombosis or prior abdominal surgery (due to prolonged resection time). ECD LTx is discussed with patients during their initial visit with the transplant hepatologist and subsequently during their appointment with the transplant surgeon. While the ECD discussion with patients is not formally standardized across providers, the general risks/benefits of ECD LTx are described and patients are informed that willingness to accept an ECD liver offer may lead to LTx sooner than SCD LTx and it may reduce their mortality risk on the waiting list. Additionally, patients are informed that they can pursue live donor LTx at another program or deceased donor LTx in another region, which may reduce the time they would otherwise have to wait for LTx at our program. Finally, all patients attend a 90-min LTx orientation class, which includes a discussion of ECD LTx, multiple listing and live donor LTx.

Assessment

Study patients completed a 20–30 min scripted interview and questionnaire assessment. Patients first were reminded of the distinction between SCD and ECD livers. At our program, ECD livers included donors >60 years old, macrosteatosis >30%, microsteatosis >60%, prolonged CIT (>12 h), imported from outside region 1, partial/split grafts, HCV + donors, anti-HBc positive donors and DCD. Next, they were told that ECD livers may shorten the wait for LTx, thus reducing the mortality risk while on the waiting list and potentially preventing further decline in quality of life (QOL). However, they were also told that ECD LTx may increase risk of medical complications and earlier graft failure compared to SCD LTx. Following this introduction, patients were asked: (1) in general, *right now*, how willing are you to accept a liver donated from a person whose medical characteristics are *ideal* (a 'standard criteria donor' or SCD liver)? (2) In general, *right now*, how willing are you to accept a liver donated from a person whose medical characteristics may be *less than ideal* (an 'expanded criteria donor' or ECD liver)? (1 = not at all willing, 2 = very unwilling, 3 = somewhat unwilling, 4 = uncertain, 5 = somewhat willing, 6 = very willing, 7 = extremely willing). Next, patients were informed that the overall 1-year mortality risk following SCD LTx was 10%, based on program-specific SRTR data at study initiation (2). Patients then used a visual proportion scale (0–100%) to indicate the 1-year mortality risk they were willing to accept after ECD LTx. The interview script, rating scale and visual proportion scale are available upon request.

The patients also completed the SF-36v2 (10) to assess health-related QOL across eight domains: physical functioning (the extent that health limits physical activities), role functioning—physical (the extent that physical health interferes with work or other daily activities), role functioning—emotional (the extent that emotional problems interfere with work or other daily activities), bodily pain (the intensity of pain and the effect of pain on activities), general health (personal evaluation of health, health outlook and perceived resiliency to illness), vitality (the extent of feelings of energy vs. feelings of fatigue), social functioning (the extent that physical health or emotional problems interferes with social activities) and mental health (general mental health, including depression, anxiety and positive affect). These domains yield two composite scores—physical component summary (PCS) and mental component summary (MCS). These scales are standardized to the general population with a mean score of 50 and a standard deviation of 10. Higher scores reflect better QOL.

Information was obtained about patient age, sex, race, marital status, education and employment status. Additionally, we extracted the following data from the medical record: primary liver disease etiology, time on the waiting list, symptoms of hepatic decompensation and current disease severity. Two disease severity indices were used. First, the most recent laboratory model for end-stage liver disease (MELD) was calculated as follows: $\text{MELD} = [0.957 \times \log_e(\text{creatinine}) + 0.378 \times \log_e(\text{bilirubin}) + 1.12 \times \log_e(\text{international normalized ratio}) + 0.64] \times 10$. For patients with additional exception points (e.g. hepatocellular carcinoma), both the lab MELD and the MELD score with exception points were recorded. Second, the Child–Turcotte–Pugh (CTP) (11,12) score was calculated based on the presence and grade of encephalopathy, the presence and severity (mild/moderate or severe) of ascites, bilirubin, albumin and prothrombin time or international normalized ratio at time of study enrollment. Patients were stratified into three groups based on CTP scores of 5–6 (A), 7–9 (B) and 10–15 (C).

Statistical analysis

Data were expressed as means and standard deviations, medians or percentage of participants with specific responses. Willingness to accept ECD LTx and ECD mortality risk were evaluated for normality using Q–Q plots and tests of skewness and kurtosis, which provided evidence of normal distributions. Univariable relationships between sociodemographic characteristics and the ECD LTx willingness and increased mortality risk variables were examined using t-test, analysis of variance or Pearson correlation coefficient. Variables significantly associated with ECD LTx outcome measures were entered in a stepwise manner into linear regression analyses to identify significant predictors of ECD LTx willingness and increased mortality risk. Statistical significance was operationalized as a probability value of ≤ 0.05.

Results

Participant recruitment and characteristics

As shown in Figure 1, 229 adults were on the LTx waiting list at some point during the enrollment period. However, 64 patients were not eligible due to being inactive on the list (n = 24), not medically eligible for ECD LTx or did not recall an ECD discussion with physician (n = 23), non-English speaking (n = 9), had a previous LTx (n = 4), or listed for liver-kidney transplantation (n = 4). Of the remaining 165 patients, 33 were excluded due to no enrollment opportunity (n = 22) or acute illness (n = 11). Another 24 patients declined participation and 4 patients consented but did not complete the assessment due to time constraints. The

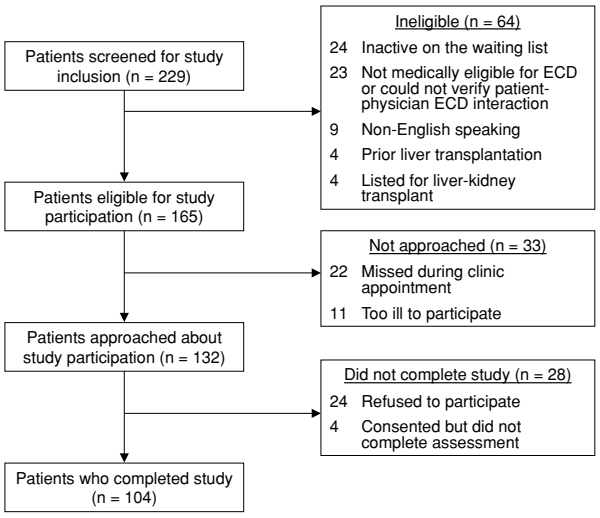

Figure 1: Diagram showing recruitment and participation rates.

participation rate for eligible patients who were approached for the study was 79%.

The sample was predominantly middle aged, male, white, married and college educated (Table 1). The most common LTx indications were viral hepatitis (51% HCV, 3% HBV), alcohol (25%), autoimmune or cholestatic diseases (8%) and nonalcoholic steatohepatitis or cryptogenic (7%). One-third (34%) had hepatocellular carcinoma. Most (80%) had one or more manifestations of clinical decompensation, including a history of ascites (65%), encephalopathy (39%) and variceal bleeding (23%). The mean lab MELD score was 15.1 (±7). With exception points, the mean MELD score was 19.4 (±7), with a categorical breakdown as follows: MELD $\leq$ 15 (39, 38%), 16–24 (36, 35%) and $\geq$ 25 (29, 28%). The mean CTP score was 8.4 (±3), with 30 (29%) in A category, 40 (38%) in B category and 34 (33%) in C category. Patients did not differ significantly from the total wait-listed population at our center, except that a higher proportion of study patients had viral hepatitis (54% vs. 35%, $p = 0.02$).

Willingness to accept SCD or ECD LTx

Patients reported significantly higher willingness to accept SCD versus ECD LTx (mean rating of 6.4 ± 0.9 vs. 4.0 ± 1.7, $t = 13.8$, $p < 0.001$). For descriptive purposes, we categorized patients as unwilling (rating of 1, 2 or 3), uncertain (rating of 4) or willing (rating of 5, 6 or 7) to accept SCD or ECD. No patients were unwilling to accept SCD LTx, although five patients (5%) were unsure about whether they wanted to receive LTx even from a SCD. In contrast, 40 (38%) and 22 patients (21%) were unwilling to accept or uncertain about accepting ECD LTx, respectively (Figure 2).

Table 1: Patient characteristics (n = 104)

	Mean ± SD or N (%)
Age, years	54.4 ± 9
Sex, female	30 (29%)
Race	
Caucasian	82 (79%)
African American	9 (9%)
Hispanic	7 (7%)
Asian	4 (3%)
Other	2 (2%)
Employed, yes	31 (30%)
Marital status	
Single, never married	27 (26%)
Single, previously married	22 (21%)
Married	55 (53%)
Highest education achieved	
Did not graduate high school	8 (8%)
High school graduate or equivalent	43 (41%)
Some college course, but no degree	22 (21%)
College graduate	25 (24%)
Professional degree	6 (6%)
Body mass index	28. 8 ± 5.4
Disease etiology	
Viral hepatitis	56 (54%)
Autoimmune or cholestatic diseases	8 (8%)
Metabolic	2 (2%)
Nonalcoholic steatohepatitis/cryptogenic	7 (7%)
Alcohol	26 (25%)
Other	5 (5%)
Hepatocellular carcinoma	35 (34%)
History of ascites	68 (65%)
History of encephalopathy	41 (39%)
History of variceal bleeding	24 (23%)
MELD score, without exception points	15.1 ± 7
MELD score, with exception points	19.4 ± 7
CTP score at transplant	8.4 ± 3
Time on waiting list, months	16.5 ± 13

MELD, model for end-stage liver disease; CTP, Child–Turcotte–Pugh.

Patients' acceptable ECD LTx one-year mortality risk

The median ECD LTx 1-year mortality rate patients were willing to accept was 25% (range = 0–85%). To derive the *increased* ECD LTx 1-year mortality risk patients were willing to accept, we subtracted the 1-year 10% mortality risk for SCD LTx from the ECD LTx mortality risk patients were willing to accept. As illustrated in Figure 3, 30 (29%) patients were willing to accept no or minimal ($\leq$5%) additional mortality risk, 49 (47%) were willing to accept moderately higher additional mortality risk (10–25%) and 25 (24%) were willing to accept substantially higher additional mortality risk (>25%).

Univariable and multivariable predictors of ECD willingness and mortality risk acceptability

In the univariable analyses, white patients were more willing to accept ECD LTx (mean rating of 4.2 vs. 3.3, $t = 2.1$, $p = 0.03$) and were willing to accept higher additional ECD LTx 1-year mortality risk (20% vs. 11%, $t = 2.0$,

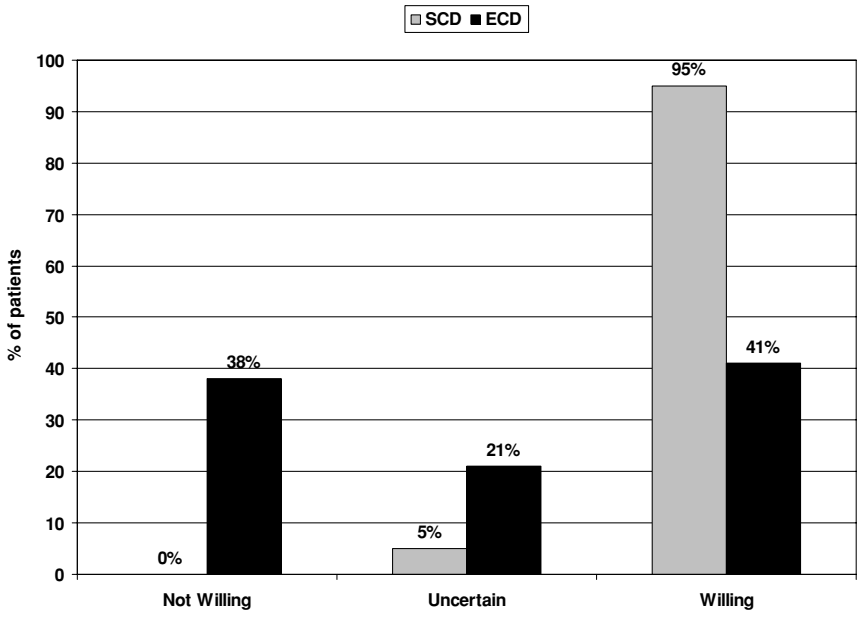

Figure 2: Proportion of study participants (n = 104) unwilling (rating = 1–3), uncertain (rating = 4) or willing (rating = 5–7) to accept standard criteria donor (SCD) and expanded criteria donor (ECD) liver transplantation.

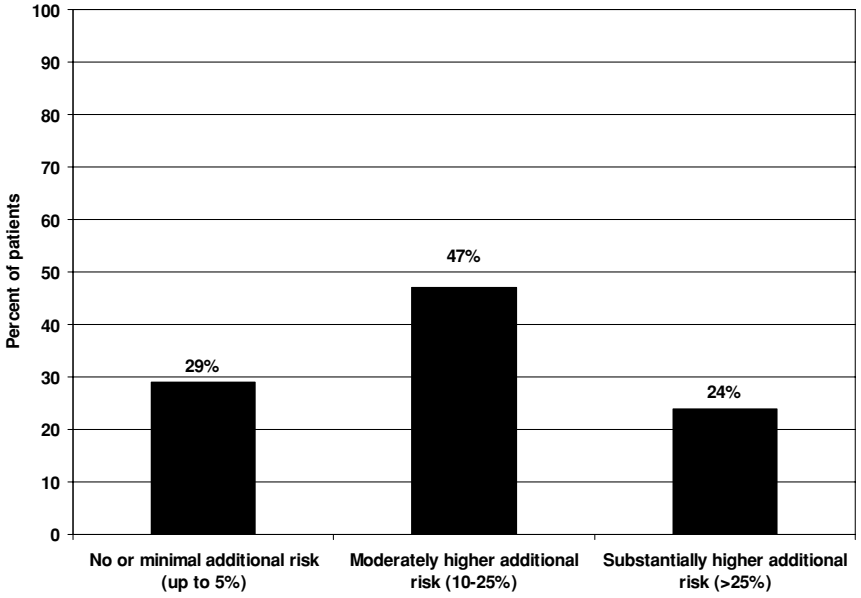

Figure 3: Proportion of study participants (n = 104) willing to accept no or minimal, moderately higher or substantially higher additional 1-year mortality risk with expanded criteria donor (ECD) liver transplantation, compared to a 10% mortality risk with standard criteria donor (SCD) liver transplantation.

p = 0.049) than nonwhite patients. A higher willingness to accept ECD LTx was significantly associated with higher lab MELD score (r = 0.40, p < 0.001; Figure 4), history of hepatic encephalopathy (4.5 willingness rating with history vs. 3.6 willingness rating without history, t = 2.4, p = 0.016) and lower physical QOL (PCS score, r = –0.30, p = 0.003). Higher additional 1-year mortality risk acceptance following ECD LTx was significantly associated with higher willingness to accept ECD LTx (r = 0.30, p = 0.002), higher lab MELD score (r = 0.21, p = 0.03), history of ascites (21% 1-year additional mortality risk acceptance with history vs. 12% 1-year additional mortality risk acceptance without history, t = 2.1, p = 0.04) and lower physical QOL (PCS score, r = –0.22, p = 0.03; bodily pain, r = –0.20, p = 0.04; physical functioning, r = –0.21, p = 0.04). No other sociodemographic (age, sex, marital status, education, employment) or clinical (waiting time, primary disease, hepatocellular carcinoma, MELD with exception points, CTP score) characteristics were significantly associated with ECD LTx willingness or increased mortality risk acceptability.

The multiple linear regression model summaries for both ECD willingness and ECD increased mortality risk acceptability were statistically significant (adj $R^2 = 0.28$, F = 9.4, p < 0.001 and adj $R^2 = 0.12$, F = 3.1, p = 0.02, respectively). In both models, higher lab MELD score (ECD willingness: $\beta = 0.43$, t = 4.8, p < 0.001; ECD increased

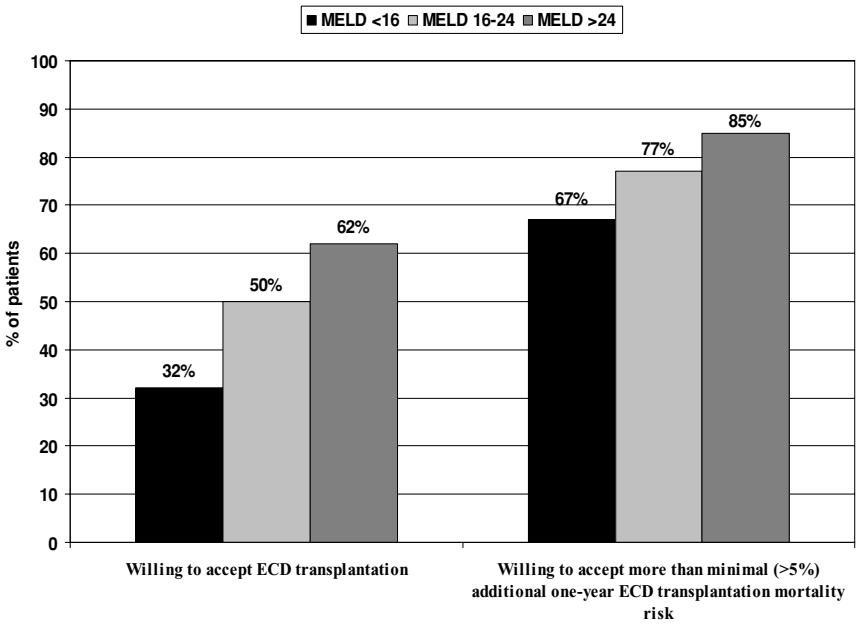

Figure 4: Proportion of study participants willing to accept ECD liver transplantation and willing to accept additional 1-year mortality risk with ECD liver transplantation, by lab MELD score.

mortality risk acceptance: $\beta = 0.24$, $t = 2.5$, $p = 0.02$) and white race (ECD willingness: $\beta = 0.26$, $t = 3.0$, $p = 0.003$; ECD increased mortality risk acceptance: $\beta = 0.22$, $t = 2.3$, $p = 0.02$) were significant independent predictors. Higher willingness to accept ECD LTx was a significant predictor ($\beta = 0.30$, $t = 3.2$, $p = 0.002$) in the ECD increased mortality risk acceptability model.

Discussion

LTx programs are increasingly accepting ECD livers, although there is discussion about the relative benefits and limitations of these organs (6,7,13–16). We report data examining patients' willingness to accept ECD LTx and its predictors. There were three main findings: (1) patients were significantly less willing to accept ECD versus SCD LTx, (2) most patients were willing to accept a 1-year ECD LTx mortality risk that is higher than that expected for SCD LTx and (3) higher lab MELD score and white race significantly predicted ECD LTx willingness and higher ECD LTx 1-year mortality risk acceptability.

More than half of the study patients reported a low willingness to accept ECD LTx and one-third were unwilling to consider ECD LTx. We did not ask study patients whether they had communicated their ECD willingness to their LTx providers, but this finding of low willingness was more prevalent than we anticipated. Some study patients verbally consented to receive ECD liver offers to maximize their transplant options, but it is clear that many of them place significantly higher value and hope on receiving SCD LTx. One-third of patients indicated that they would not accept an ECD liver offer at this point in time. A relatively high proportion of study patients had low to moderate disease severity, which could explain the higher than anticipated rate of ECD LTx unwillingness. Also, it is possible that many patients prefer to stick with the SCD LTx option and risk omitting the ECD LTx option rather than actively choose the ECD LTx option and risk committing a mistake. It is possible that some patients are risk averse and may not be able to cope effectively with medical uncertainty, thereby avoiding ECD LTx altogether.

Not surprisingly, patients with a higher lab MELD score were more willing to accept ECD LTx and higher 1-year post-LTx mortality risk than those associated with SCD LTx. Since the MELD score is a reflection of the short-term survival probability without LTx, patients with higher MELD scores may feel a sense of urgency in trying to best balance the ECD LTx mortality risk with their risk of death while waiting for a higher quality SCD organ offer. What is interesting, however, is that the significant relationship between the MELD score and ECD LTx willingness dissipates when examined in the context of MELD scores with exception points. One might reasonably hypothesize that patients with hepatocellular carcinoma, faced with malignancy and the likelihood of tumor progression, would be much more willing to accept an ECD liver than those without liver cancer. Our data do not support this hypothesis, as those with hepatocellular carcinoma did not differ from other patients in their ECD LTx willingness and MELD score with exceptions was not associated with ECD LTx willingness or mortality risk acceptability.

Some patients may be more willing to pursue ECD LTx if it reduces their waiting time by several months, although the precise time threshold that patients may use in making this decision is currently unknown and is likely to be influenced by a variety of factors. For instance, it is possible that some

patients considered mortality risk acceptability in comparison to their perceived risk of dying of their liver disease without a transplant, information we did not specifically provide to them as part of this study. In general, however, these data provide some ecological support for Amin et al. (17) decision modeling analysis showing that patients with higher MELD scores may have the most to gain from immediate transplant with ECD liver grafts. It is important to emphasize, however, that changes in lab MELD score over time may influence willingness to accept ECD LTx. For instance, patients with upward trajectory in lab MELD score may have different perspectives on ECD LTx than those with a stable lab MELD score or those who have recovered from a high MELD score following an acute medical event. The relationship between lab MELD score patterns and ECD willingness warrants further investigation.

Contrary to what we anticipated, some indices of disease severity (e.g. encephalopathy, ascites) and functional status (e.g. QOL), while significant in the univariable analyses, did not predict ECD LTx willingness or increased mortality risk acceptability in our multivariable models. In our transplant program, the MELD score has a central presence in our discussions with patients, especially as it relates to proximity to transplantation and wait-list mortality. Symptoms of hepatic decompensation and its impact on QOL are important, but patients are informed through our educational materials and clinic interactions that the frequency and severity of these symptoms do not correspond directly with their relative status on the LTx waiting list. Therefore, some patients with ascites, encephalopathy, and a poor QOL but with a low lab MELD score may not feel the same sense of urgency to consider ECD LTx as the patient with a similar symptom profile and a high lab MELD score.

Race was a significant predictor in the multivariable analyses, with nonwhite patients reporting less willingness to accept an ECD liver and less likely to accept increased mortality risks. Some caution should be exercised in interpreting this finding since minorities represented fewer than one-quarter of the sample and, therefore, were combined into one minority group for analysis purposes. Nevertheless, there is evidence cultural values and beliefs inform the transplant treatment decisions of minorities (18,19). Mistrust of the healthcare system, including organ allocation and transplantation processes, is prevalent in minority communities (20–22). Such mistrust may be magnified as it pertains to ECD LTx since the transplant community has not clearly articulated and agreed upon a uniform distinction between standard and extended criteria donors, the short- and long-term risks associated with ECD LTx, and which patients are most likely to benefit from accepting an ECD allograft liver. LTx racial disparities are well documented (23–25) and minorities, especially those with high mistrust of the healthcare system and low levels of health literacy, may be less willing to participate in an ECD allocation system that may perpetuate perceptions of racial disparity. A culturally and linguistically competent approach to discussing ECD LTx with minority patients may facilitate better understand of this transplant option and its potential risks/benefits (26). A further study of the barriers to ECD acceptance in minority patients is needed.

While this was the first study to examine ECD LTX willingness and benefited from a high participation rate, findings should be interpreted in the context of several limitations. Patients who chose to take part in this study may have differed nonrandomly from those who refused to participate. This is a single-center study and findings should not be generalized beyond the sociodemographic characteristics of this sample. Our assessment was made at one point in time and, therefore, represents a single snapshot view of ECD LTx willingness. It is likely that patients' willingness to accept ECD LTx and potentially higher mortality risk change over time, and we do not know whether ECD willingness predicts actual behavior at the time of organ offer. Furthermore, we were not able to evaluate whether repeated exposure to ECD (i.e. more discussions with providers) may contribute to more favorable attitudes and a higher willingness to pursue this transplant option. While all study patients were informed of the ECD LTx option, the nature, duration and nuances of the ECD LTx discussion in the context of clinical care likely varied from one provider to another. Finally, there is no consensus on what defines an ECD liver. Therefore, an ECD definition that differs from the one used in the current study may yield different findings. We recognize that organ quality (and subsequent risk of graft failure) exists along a continuum and that our assessment dichotomized ECD versus SCD LTx in a way that does not reflect the full range of organ quality and associated risks. Many factors influence how patients assess risk, including their numerical literacy, the quality of the provider–patient relationship, and emotional process, which were not assessed in the current study (27,28).

Important areas for future study include examining specific reasons why patients are not willing to accept ECD LTx; how different types of ECD livers affect patients' decision-making; the correspondence or agreement between individual patients and their providers on measures of ECD LTx willingness and increased mortality acceptability; methods for effectively communicating ECD risk information to patients; the relationship between race, health literacy, cultural beliefs and willingness to consider ECD LTx; changes in willingness to accept and ECD LTx over time as disease progresses; and the association between willingness to accept ECD LTx and actual clinical-decision making at the time of an ECD liver offer.

In conclusion, for both patients and providers, ECD LTx is a complex medical decision in which the patient's current health status, the potential health benefits to the recipient, the degree of morbidity and mortality risk and comfort with the procedure must be carefully considered. The decision to be made about whether to accept ECD LTx is often fraught with uncertainty. It is important to

repeatedly assess patients' willingness to pursue ECD LTx and the relative mortality risks they are willing to accept. This may provide an opportunity to clarify any misperceptions or concerns the patient may have about this type of transplantation. Also, there is some evidence that patients who receive psychoeducational interventions to manage uncertainty are better able to make treatment decisions and to feel comfortable about them (29). Without a dramatic increase in SCD livers, ECD LTx is likely to remain a viable option for increasing access to transplantation, reducing the median wait time for transplantation and lowering the waiting list mortality.

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Disclosure

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