MELD Scores of Liver Transplant Recipients According to Size of Waiting List Impact of Organ Allocation and Patient Outcomes

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In the last decade, considerable controversy has surrounded the allocation of deceased-donor (DD) livers in the United States. Under the old allocation system (used until February 28, 2002) in which priority for transplantation was based primarily on waiting time and subjective measures of urgency, inequalities developed in the procurement and allocation of DD livers. Specifically, there were large disparities in waiting times across geographic regions, as well as difficulties in fairly prioritizing patients for transplantation because the assessment of the severity of illness for patients awaiting transplantation included subjective criteria. As a result, the US Department of Health and Human Services issued a regulation in 1998, referred to as the "final rule," to ensure "that allocation of scarce organs [would] be based on common medical criteria, not accidents of geography." The final rule "provide[d] a framework within which the transplant system would operate. The stated principles underlying the 'Final Rule' include the creation of a 'level playing field' in organ allocation—that is, organs are allocated based on patients' medical need and less emphasis is placed on keeping organs in the local area where they are procured." After issuance of the final rule, many members of the transplant community voiced strong opposition to its implementation. Opponents feared that the final rule would result in the closure of small programs, limit access to transplantation, and decrease organ donation. Consequently, Congress suspended implementation of the final rule for 1 year and asked the Institute of Medicine (IOM) to conduct an independent review to determine the rule's impact on transplantation. The IOM review made 2 principal recommendations relative to allocation of DD livers:

- Establishment of organ allocation areas serving a population base of 9 mil-

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lion people. This recommendation was based on strong statistical evidence that increasing the size of the organ allocation area would increase the number of transplants for sicker patients without adversely affecting less-sick patients.

- Deemphasis of waiting time as an allocation criterion for transplantation. A further recommendation was that the liver allocation system be based on an objective point system, including medical characteristics predictive of prognosis.

During the subsequent 4 years, the Model for Endstage Liver Disease (MELD) score was developed, studied, and finally implemented in February 2002 and serves as the basis for the liver allocation system used by the United Network for Organ Sharing. The MELD score reflects the recommendations of the IOM review and the final rule in that its basis is an objective scoring system of medical characteristics predictive of prognosis, with minimal emphasis on waiting time as a priority for transplantation. However, the IOM recommendation to increase and standardize the size of the area of organ allocation has not been implemented. Consequently, there is great disparity in the patient populations served by organ procurement organizations (OPOs) across the country. This disparity is seen in the total number of residents within a given OPO, as well as the number of patients listed for liver transplantation. In some regions of the United States, an OPO may serve as few as 1.2 million people, whereas in other areas, the population covered by the OPO is nearly 18 million. The difference in the number of patients listed for transplantation within OPOs is even greater. The smallest OPO has fewer than 10 patients listed for liver transplantation, whereas the largest has more than 2000. As we discovered, the difference in the number of patients listed for transplantation within an OPO is the most important reason for the disparity in MELD scores in transplant recipients between OPOs.

We have noted that, in specific geographic areas of the country where patients receive transplants in OPOs with small waiting lists, the goals of the final rule are not achieved; that is, organs are retained in the small OPO and transplanted into less-sick patients whose outcomes are identical to those of sicker patients receiving transplants in nearby large OPOs. We describe this observation and comment on its relevance to organ allocation and patient outcomes.

METHODS

The distribution of MELD scores was recorded for adult DD liver transplant recipients and adult patients listed for liver transplantation between February 28, 2002, and March 31, 2003, in each OPO where liver transplantations are performed, by using data from the Scientific Registry of Transplant Recipients (SRTR) and the Organ Procurement and Transplantation Network. The SRTR reports the distribution of MELD scores between 6 and 10, 11 and 18, 19 and 24, and 25 and 40. MELD scores were based on laboratory values at reference (i.e., either at or while listed for transplantation). If all of the necessary laboratory values were not available, the patient was assigned a MELD score of 6. We designated the OPOs as “small” if fewer than 100 patients were listed for liver transplantation within the OPO and “large” if at least 100 patients were listed (as of July 2002). Patient and graft survival were assessed between January 1, 2000, and June 30, 2002. The rate of transplantation and the percentage of patients removed from the waiting list because of death were also recorded. Estimates of population within the OPO were based on the list of counties within the OPO and population estimates by county using data from the US Census Bureau. Comparisons between patient groups were made with $\chi^2$ analysis or $t$ test where appropriate.

Organ-sharing agreements exist in several areas of the United States and differ widely from region to region. In our analysis, the OPOs in New York and Tennessee were analyzed as 1 OPO because all patients listed at liver transplant programs in the respective states are maintained on a single list.

The Colorado Multi-institutional Review Board waived the necessity of “approval” because no patient identifiers are used in this analysis.

RESULTS

Twelve of 50 (24%) OPOs where liver transplantation is performed are small and the remaining 38 are large. Of the 4798 DD liver transplantations performed between February 28, 2002, and March 31, 2003, 398 (8.3%) were transplanted in small OPOs.

The distribution of MELD scores for patients listed for liver transplantation was the same in large and small OPOs: 92% had a MELD score of 18 or lower, 7% had a MELD score between 19 and 24, and only 2% of listed patients had a MELD score higher than 24 ($P=0.85$). The death rate per years on the transplantation list (waiting list mortality rate) was similar for patients in small (0.126) and large (0.122) OPOs. The rate of transplantation (per years listed) was 2.5-fold higher for patients listed in small OPOs (1.03) vs large OPOs (0.41) ($P<0.001$). The distribution of MELD scores for liver transplant recipients in small and large OPOs is shown in the Figure. Patients receiving transplants in small OPOs were less sick at transplantation than those in large OPOs. The proportion of patients who received a transplant and had a MELD score between 11 and 18 was 2-fold higher in small OPOs (47%) compared with large OPOs (23%) ($P<0.001$). The proportion of patients who received a transplant and had a MELD score higher than 24 was more than 2.5 times higher in large OPOs (49%) than in small OPOs (19%) ($P<0.001$). Patient survival rates at 1 year after transplantation for small OPOs (86.4%) and large OPOs (86.6%) were not statistically different ($P = 0.59$), and graft survival rates in small OPOs (80.1%) and large OPOs (81.3%) were not statistically different ($P = 0.80$).

In small OPOs, the number of OPO residents (donor pool) divided by the number of listed patients (109215) was more than 4-fold higher than in large OPOs (21867) ($P = 0.003$). Within the
OPO, the number of livers procured in the OPO divided by patients listed for transplantation was significantly higher in small OPOs (1.23) compared with large OPOs (0.29) \(P < .001\).

**COMMENT**

The implementation of the MELD score as the basis for DD liver allocation has improved the distribution of organs. Deceased-donor livers are preferentially transplanted into sicker patients, which has reduced waiting list mortality without reducing posttransplantation survival.\(^3\) However, considerable disparity in MELD scores for liver recipients still exists between small and large OPOs. This inequality is a direct result of 3 issues. First, although a number of states and regions have sharing agreements, which are designed to increase allocation of DD livers to sicker patients, the current national allocation policy dictates that, in general, DD livers be allocated to the patient with the highest MELD score within the OPO where the organs are procured. The most notable exception is for acute liver failure, in which the organ is usually allocated to the sickest patient in the United Network for Organ Sharing region (composed of several contiguous states). However, acute liver failure is an uncommon indication for transplantation.

Second, the mean number of patients listed in small OPOs (43) was lower compared with that of large OPOs (462). In addition, only 2% of all patients listed (in small and large OPOs) had a MELD score higher than 24. Therefore, in small OPOs in which a mean of 43 patients are listed for transplantation, no patients or only 1 patient is likely to have a MELD score higher than 24 at any given time. However, in large OPOs, where more than 400 patients on average are listed, the number of patients with a MELD score higher than 24 is likely to be 8 or more. Consequently, the absolute number of patients with severe end-stage liver disease (MELD score >24) in large OPOs is substantially higher than that of small OPOs. As a result, when an organ becomes available, large OPOs are more likely to have a patient with a higher MELD score (>24) available to receive the organ compared with a small OPO.

Third, patients listed in small OPOs receive transplants at a much higher rate (2.5-fold) than patients listed in large OPOs. The rate at which patients receive transplants is directly related to the number of organs available (per listed patient), which is much higher in small OPOs where the mean number of residents (in the OPO) per patient listed is approximately 100000 compared with fewer than 30000 in large OPOs. As a result, the number of DD livers procured in the OPO per patient listed is substantially higher in small OPOs. The higher rate of transplantation in small OPOs may allow patients to receive transplants before decompensation, which frequently develops in patients with extended waiting time on the transplantation list.

The reason that small OPOs have fewer listed patients and a relatively larger donor pool is unclear, although there are several possible explanations. Almost all of the small OPOs are based in moderate-sized cities (population 1 million to 2 million), and the majority of the large OPOs are based in large metropolitan areas (population >4 million). Patients with end-stage liver disease who reside in smaller cities may seek transplantation services in large transplant centers and travel to larger metropolitan areas, where these transplant centers are located. Alternatively, patients with end-stage liver disease may relocate their residence to bigger cities with large transplant programs. In addition, the proportion of residents in large metropolitan areas who are diagnosed as having end-stage liver disease and subsequently referred for liver transplantation could be higher than in smaller cities.

There are advantages and disadvantages to the disparity in MELD scores of transplant recipients in small and large OPOs. From the patient’s standpoint, there may be advantages to receiving a transplant in a small OPO. Once listed, the patient receives a transplant much faster and at a lower MELD score than in larger OPOs. This may allow the transplant to occur before clinical decompensation, which can harm the patient’s quality of life before transplantation and compromise posttransplantation recovery. Another potential advantage is increased access to transplantation services within the local area. Preferential allocation of livers to sicker patients in large OPOs could reduce access to transplantation within the local community of the small OPO. As a result, patients would have to travel a greater distance for transplantation services. Although on average this distance would be small because the mean distance between a small OPO and the nearest center in a large OPO is 140 miles, patients with limited resources might have greater difficulty traveling to the transplant center for evaluation, transplantation, and follow-up care.

From an allocation standpoint, there are clear disadvantages to transplanting less-sick patients in small OPOs. For patients and physicians who have options in selecting a transplant center,
the consequences of choosing a center in a small OPO may be transplantation at a lower MELD score, with no difference in waiting-list mortality and patient or graft survival after surgery. Therefore, selection of a center in a small OPO offers no objective advantage for the patient. Choices in selection of a transplant center may exist for many patients because the distance separating transplant centers in small and large OPOs is small. Another implication of the disparity in the current allocation system is the inability of sicker patients in large OPOs to access DD livers from nearby small OPOs. Although their MELD score may be substantially higher than that of recipients in a small OPO, patients waiting for transplants at a center in a large OPO may not have access to DD livers procured in an adjacent small OPO. Finally, the inequalities in allocation directly contradict the stated goal of the final rule, which is the "...creation of a 'level playing field' in organ allocation—that is, organs are allocated based on patients' medical need and less emphasis is placed on keeping organs in the local area where they are procured."

The disparity in MELD score that we have demonstrated would likely be resolved by increasing the size of the population served by the OPO. The IOM found that the optimal size of the organ allocation area was 9 million people. Increasing the size of the organ allocation area to 9 million people would increase the number of transplants in sick patients with urgency for transplantation without affecting the outcome of less-sick patients. In some regions of the country, the area of organ allocation is increased by the creation of organ-sharing agreements between OPOs. These agreements provide more equitable allocation of DD livers, with preferential allocation to sicker patients. However, increasing the size of the organ allocation area could harm other important aspects of transplantation, including a likely decrease in the number of centers performing liver transplantation. As a result, patients would have to travel farther to receive transplantation services. Consequently, patients with limited resources may not be able to receive liver transplants. In addition, the complexity in coordinating medical care before and after surgery would likely increase.

One explanation for the lower MELD scores in the small OPOs could be that the data from the registry do not accurately reflect the actual MELD scores of the recipients in the small OPOs. Centers in small OPOs may have less competition for DD livers compared with centers in large OPOs, where the competition for livers between centers is intense. As a result, the transplant center in the small OPO may not need to be as vigilant in updating the MELD score as centers in large OPOs. Therefore, the MELD scores for recipients receiving transplants in small OPOs could actually be higher than the scores recorded in the SRTR database. However, we believe that this situation is unlikely.

There are 2 important issues about the data in our analysis. First, the MELD scores used in this analysis do not reflect MELD scores assigned to patients for the diagnosis of hepatocellular carcinoma. Patients with hepatocellular carcinoma are assigned 20 points for limited-stage disease (T1) and 24 points for extensive-stage disease (T2). As a result, the MELD scores in our analysis reflect the severity of illness in patients according to laboratory values alone. Second, the patient and graft survival rates reported here are from a different interval (January 2000 to June 2002) than MELD scores of transplant recipients (February 2002 to March 2003). Therefore, most data on patient and graft survival reflect outcomes before the initiation of the MELD system.

In summary, we report that a significantly smaller proportion of adult DD liver transplant recipients in OPOs with small waiting lists receive transplants and have a MELD score higher than 24 compared with recipients in large OPOs. The most likely explanation for this disparity is that DD livers are preferentially retained for transplantation in the local OPO, where the number of patients with high MELD scores is smaller than that in large OPOs. Although this disparity does not reflect the mandate of the final rule, there may be advantages for selected patients. Transplant professionals should be aware of this disparity and its implications as they continue to amend regulations for organ allocation.

Author Contributions: Dr Trotter had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design, analysis and interpretation of data, and drafting of the manuscript: Trotter. Acquisition of data and critical revision of the manuscript for important intellectual content: Trotter, Osborn.

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REFERENCES