Model for End-stage Liver Disease

Did the New Liver Allocation Policy Affect Waiting List Mortality?

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Objective: To examine the impact of the Model for End-stage Liver Disease (MELD) on waiting list mortality.

Design: Interrupted time series with a nominal inception point of the intervention on February 27, 2002.


Participants: All adult candidates on the waiting list for liver transplantation in the United States during the study period.

Intervention: Implementation of the MELD policy.

Main Outcome Measures: Waiting list mortality, waiting time to transplantation, number of new registrants, and posttransplantation survival.

Results: Although no preintervention trend was identified, the policy change was associated with an immediate effect of increasing waiting list mortality by 2.2 deaths per 1000 registrants per month (from approximately 11 to 13 deaths per 1000 registrants per month; 95% confidence interval [CI], 1.1 to 3.4; \( P = .001 \)) followed by a postintervention decline in waiting list mortality over time (−0.09 death per 1000 registrants per month; 95% CI, −0.16 to −0.03; \( P < .001 \)). An immediate effect of decreased waiting time was also noted (from approximately 294 to 250 days; −44.4 days; 95% CI, −77.1 to −11.7 days; \( P < .001 \)), which reached a new, lower postintervention steady state. The intervention had no effect on the number of new registrants listed per month or on 3- and 6-month posttransplantation survival.

Conclusion: After an initial increase in waiting list mortality, the implementation of the MELD-based allocation policy was associated with an overall decline in waiting list mortality and time to transplantation.

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In the past decade, the prevalence of end-stage liver disease has increased exponentially; however, the rate of organ donation has remained relatively stable. The net effect is the current critical organ shortage. Since 1991, a greater than 10-fold increase in the number of liver transplantation candidates on the waiting list has occurred; however, only a 2-fold increase in the number of donor livers has occurred despite the evolution of living donation and split organ transplantation. In 2004, more than 17 000 patients were on the waiting list, but only 5600 patients received transplants.1

See Invited Critique at end of article

Before 1997, patients with end-stage liver disease were prioritized to receive deceased donor organs on the basis of their medical condition as reflected by their care setting at the time of transplantation and/or listing, with setting stratified as hospitalized in the intensive care unit (ICU), hospitalized but not in the ICU, or at home. Because of the large number of patients, this system relied on individual physician and/or center judgment as to the relative acuity of individual registrants. In 1998, 4 new categories of medical urgency, based on the Child-Turcotte-Pugh score, were established. Registrants were listed as either status 1 (ICU patients expected to die within 7 days without transplantation), status 2A (patients with severe liver disease but not likely to die within 7 days without transplantation), and status 2B and status 3 (which represented less-ill registrants).

However, as the population with end-stage liver disease continued to increase, the number of patients in each urgency status category climbed accordingly and waiting time became the major discriminator between patients within each status category. As waiting time gained importance with regard to access to transplantation, an increasing number of less-ill registrants...
were listed for the sole purpose of “banking time” on the waiting list.

These issues led the Department of Health and Human Services (DHHS) and the Institute of Medicine (IOM) to examine the national organ allocation policies. In 1999, the IOM deemed that waiting time was a poor indicator of medical urgency and that rates of transplantation, illness severity, and waiting list mortality were much more meaningful. The IOM recommended that allocation of deceased donor livers could be improved by instituting a mechanism that favored disease severity and deemphasized patient waiting time. This recommendation led the DHHS to release the final rule, which established that deceased donor liver organ allocation in the United States be based primarily on medical urgency. The DHHS assigned the task of developing such a mechanism to the United Network for Organ Sharing (UNOS) and the transplantation community.

The Model for End-stage Liver Disease (MELD) was identified as potentially meeting these requirements. MELD is an objective score based on pretransplantation laboratory data, including serum creatinine level, total bilirubin level, and international normalized ratio. MELD was initially developed and validated to predict mortality in patients with end-stage liver disease who were undergoing transjugular intrahepatic portosystemic shunt procedures. It was later validated and generalized to more heterogeneous patient populations with chronic liver disease. However, it was recognized that MELD may not be an appropriate measure of need for transplantation in certain populations, including patients with acute hepatic failure and patients with conditions in which urgency is not driven by hepatic failure but by the likelihood of disease progression that could preclude later benefit from transplantation. For the former, the status 1 category was maintained, and for the latter, MELD exceptions were established to benefit patients not well served by the MELD formulation, such as those with hepatocellular carcinoma, who often have good hepatic reserve but the potential to develop metastatic disease. The MELD score ranks patients in a continuous fashion on a scale of 6 to 40 points, and waiting time is used only to distinguish patients with identical MELD scores within blood group and region. Thus, MELD emphasizes medical urgency and deemphasizes waiting time and therefore meets the criteria set forth by the DHHS. The MELD-based organ allocation policy was adopted in the United States on February 27, 2002.

The purpose of this study was to evaluate the impact of the MELD-based allocation policy on access to transplantation and posttransplantation outcomes and, unlike previous studies, to use methods that take preintervention and postintervention secular and seasonal trends into consideration. We took advantage of a unique opportunity by using a large national database and a specific intervention time point (February 27, 2002). We hypothesized that the implementation of the MELD score in liver allocation policy led to a decrease in waiting list mortality. Our objective was to test whether the overall goal of the policy, which was intended to more appropriately allocate organs based on patient acuity and thereby decrease waiting list mortality, was accomplished.

METHODS

DESIGN OVERVIEW

The purpose of this study was to evaluate the association of access to liver transplantation and posttransplantation outcomes with changes in the organ allocation policy using data from the 1999–2004 Organ Procurement and Transplantation Network Standard Transplant Analysis and Research (STAR) files. Because of a lack of concurrent controls, an interrupted time series was used. This type of study design uses a collection of observations made sequentially in time before and after an intervention to determine its impact. Interrupted time series require a nominal inception point of the intervention, which occurred in our study on February 27, 2002, with the adoption of the MELD scoring system for deceased donor organ allocation in the United States. The primary outcome measure was mortality per 1000 waiting list registrants per month. Secondary outcome measures included mean waiting list time to transplantation, the number of new registrants per month, and 3- and 6-month posttransplantation survival.

DATA SOURCE, STUDY PERIOD, AND STUDY POPULATION

All cases were obtained from the UNOS STAR files, a registry maintained by UNOS that prospectively collects pretransplantation, transplantation, and follow-up data on all individuals on the waiting list for solid organ and intestinal transplantation in the United States. Registry data include demographic information, pretransplantation clinical and laboratory information, patient status codes used in the allocation of donor organs, and comprehensive transplantation and follow-up data. Data are collected at the time of listing, at transplantation, 6 months after transplantation, and thereafter on the transplantation anniversary for every organ recipient through the date of death. The study period was chosen to provide sufficient preintervention and postintervention time points and to optimize statistical power. The study period started on March 1, 1999, and ended on July 30, 2004. As noted previously, the intervention occurred on February 27, 2002. Using calendar month as the unit of analysis, the study had 36 preintervention and 29 postintervention time points. This approach provides sufficient time points so that secular and seasonal trends may be adjusted for in regression models.

On the basis of STAR file data as of July 30, 2004, the study population included all adult (age ≥ 18 years) liver transplantation candidates who were on the waiting list at any time during the study period and for whom the following key variables were populated: age, listing date, removal date, and reason for removal (n=60,392 registrants). Before the study, the Vanderbilt University institutional review board was contacted, and since the data were deidentified before release to our institution, no formal institutional review board review was required.

INTERVENTION

The MELD scoring system for deceased donor liver allocation in the United States became effective on February 27, 2002. MELD is an objective score that incorporates pretransplantation laboratory values for serum creatinine, total bilirubin, and international normalized ratio.

OUTCOME MEASURES

Because the IOM deemed waiting list mortality as the most appropriate indicator of access to transplantation, we selected it as the unit of analysis. The study had 36 preintervention and 29 postintervention time points. This approach provides sufficient time points so that secular and seasonal trends may be adjusted for in regression models.

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INTERVENTION

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as our primary outcome variable. Waiting list mortality was calculated as the number of patients removed from the list because of death plus the number removed from the list because they were too sick to undergo transplantation per 1000 registrants per month. In an effort to minimize selection bias, we treated these patients as a combined end point because both events represent a treatment failure of the allocation system.

In addition to waiting list mortality, we selected several secondary outcomes that were likely affected by the intervention. Because the incentive to “bank time” for less-ill recipients was no longer a strong contributor, it was likely that the intervention would affect mean waiting list time to transplantation. Similarly, with less incentive to register patients early in their disease process, the implementation of the MELD system would also likely affect the number of new registrants added to the list during a given period. We also assessed the effect of the intervention on short-term posttransplantation survival (ie, 3- and 6-month posttransplantation survival percentages). For patients receiving transplants in 2004, 6-month survival could not be ascertained because the study ended in July 2004. Thus, to analyze 3- and 6-month survival using the same cohort of patients, these analyses are restricted to patients receiving transplants through December 2003.

CONFOUNDING

Patient acuity mix within each time point that could be related to implementation of the MELD system has an effect on waiting list mortality within that time point because the more seriously ill patients are more likely to die if they do not undergo transplantation. Medical condition is reliably reported and has been consistently defined since 1987 as the patient’s location at the time of removal from the list: ICU, hospitalized but not in the ICU, or at home. Other indexes of patient acuity such as status have not been consistently defined (because of the implementation of MELD) during the study period. Therefore, medical condition was controlled for as a measure of patient acuity mix in our analyses. Patients were classified as hospitalized or not hospitalized, and the percentage of hospitalized patients per month was calculated and included in the model. In addition, variables that relate to increased organ availability likely affect waiting list mortality by improving access to transplantation. For example, the use of split and living donor grafts, collectively known as technical variant grafts, increase the donor pool and thereby alter access to transplantation. The technical variant rate was calculated as the number of split donor recipients plus the number of living donor recipients per 100 transplantations per month and was also included as a covariate in the model.

Similarly, the increasing use of marginal donors also increases the donor pool and likely changes access to transplantation. Previous studies show donor age older than 60 years to be one of the strongest predictors of posttransplantation graft and patient survival related to pretransplantation donor characteristics. On the basis of these reports, we defined a marginal donor as any donor 60 years or older, calculated the percentage of marginal donor recipients per month, and included it in the model.

Because a separate analysis showed a significant increase in the percentage of patients listed as having hepatocellular carcinoma after the implementation of MELD and current practice grants MELD exceptions and additional points for patients with hepatocellular carcinoma, the percentage of patients with hepatocellular carcinoma listed may alter access to transplantation for the registrant population as a whole. Thus, we also included the percentage of patients with hepatocellular carcinoma listed per month as a covariate in our model.

STATISTICAL ANALYSES

Segmented regression models were used to estimate the effect of implementation of the MELD scoring system on the outcome measures after adjusting for secular trends before and after intervention and the confounders and covariates described herein. We assumed a first-order autocorrelation. The series consisted of 65 monthly rates: 36 months before the intervention (from March 1, 1999, to February 28, 2002) and 29 months after the intervention (from March 1, 2002, to July 30, 2004).

A decrease in the outcome measure was determined if a statistically significant decline was observed after the implementation of the MELD scoring system. A possible effect was noted if the outcome measure showed a significant preintervention trend (either improving or worsening) but no significant change after implementation. Increases in the outcome measure were apparent if a statistically significant increase in the outcome measure was discovered after the intervention. An immediate effect represents a significant change that occurs in the first month after the intervention. Finally, no effect was interpreted if adoption of the MELD scoring system had no discernible impact on the outcome measure over time.

To assess the explanation of outcomes based on the covariates in each model, residual analysis was performed using correlograms, which were evaluated to ensure that no significant autocorrelation existed within residuals. In addition, Portmanneau Q statistics were calculated for each model, confirming that the model residuals had no significant autocorrelation. These measures supported the adequacy of each model’s covariates as important contributing factors that explained the variation in each tested outcome measure. Evaluation of all outcome measures met goodness-of-fit criteria except models that examined the number of new registrants per month.

Graphic representations of findings are presented as both unadjusted and risk-adjusted outcome measures. The unadjusted plots depict the immediate effect of the intervention on the outcome variable and associated secular trends. The adjusted plots depict the same results; however, the analysis accounted for the covariates described in the article. All analyses and graphic processing were performed using Stata statistical software, version 8.2 (Stata Corp, College Station, Texas).

RESULTS

GENERAL CHARACTERISTICS

The mean±SD age of the study population was 51±10 years, and 62.3% of registrants were male. In addition, 73.2% of registrants were white, 13.1% were Hispanic, and 7.3% were African American. Most patients (94.2%) were not hospitalized at the time of removal from the list. The mean±SD number of new registrants per month was 761±155 (range, 510-1032). The mean±SD technical variant rate was 6.4±2.2 per 100 transplantations, and the percentage of transplant recipients who received transplants from marginal donors varied from 7.9% to 20.2%, with a mean of 14.1% per month.

SEGMENTED REGRESSION RESULTS

Figures 1, 2, 3, 4, and 5 depict the unadjusted changes in the outcome measures over time and the time series changes in the outcome measures over time adjusted for the covariates included in the model. The results of the
The intervention was associated with an immediate effect of increasing waiting list mortality by 2.2 deaths per 1000 registrants per month (95% CI, −0.16 to −0.03; *P* < .001). It then reached a new, postintervention lower steady state (mean change, 0.85; 95% CI, −0.56 to 2.27). No preintervention trend was identified (mean change, 0.94; 95% CI, −0.96 to 2.8).

With regard to time on the waiting list before transplantation, the intervention had an immediate effect of decreasing time to transplantation by a mean of 60 days (mean change, −44.4 days; 95% CI, −77.1 to −11.7 days; *P* < .001), and after intervention, it reached a new, lower steady state. No preintervention trend was identified (Figure 2). Although no intervention effect or preintervention or postintervention trends were identified for the number of new registrants added to the waiting list, remarkable seasonal variability was found, with peaks in the summer months and troughs in the winter months (Figure 3). For both 3- and 6-month survival, no preintervention, intervention, or postintervention trends were identified (Figures 4 and 5, respectively).

This study provides initial evidence that the implementation of the MELD-based liver allocation policy has been associated with its intended goal of improving access to transplantation as represented by decreased waiting list mortality and waiting time to transplantation. Furthermore, short-term posttransplantation survival was not significantly affected by the policy change. The approach used in this study has several strengths. The use of a large

autoregressive integrated moving average model for the primary outcome measure of death rate per 1000 registrants are given in the Table. Although no significant preintervention trend has been identified, the intervention is associated with an immediate effect of increasing waiting list mortality by 2.2 deaths per 1000 registrants per month (from approximately 11 to 13 deaths per 1000 registrants per month; 95% confidence interval [CI], 1.1 to 3.4; *P* = .001) followed by a steady postintervention decline in waiting list mortality by 0.09 death per 1000 registrants per month (95% CI, −0.16 to −0.03; *P* < .001).

Overall, the intervention was associated with a slight decline in waiting list mortality over time (Figure 1).

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national database with mandatory reporting of all transplantation candidates in the United States provides almost complete capture of the study population. Also, the interrupted time series method has several distinct advantages over other nonrandomized designs, including before-after studies, and is considered by some to be the gold standard for observations program and policy evaluations.14 Interrupted time series analysis evaluates preintervention and postintervention trends and accounts for serial correlation. These designs also have the power to test and correct for seasonal patterns and outliers.

Since MELD was developed at the Mayo Clinic (Rochester, Minnesota) in 2000, evaluation of the model has primarily focused on its ability to predict both pretransplantation and posttransplantation survival.3 In 2002, Salerno et al13 further validated MELD as a strong predictor of 3-month survival in patients with end-stage liver disease undergoing transjugular intrahepatic portosystemic shunt procedures. Other published studies5-9 support MELD as a strong predictor of mortality in a heterogeneous population of patients with end-stage liver disease. However, Merion et al16 suggest that ΔMELD (ie, change in MELD score over time) is more predictive of short-term pretransplantation mortality than the patient’s initial MELD score or urgency status. Although Edwards and Harper17 also reported a high concordance of MELD with pretransplantation mortality for both new registrants and relisted registrants (C statistic = 0.85 and 0.79, respectively), the concordance with posttransplantation survival was low (C statistic = 0.53 and 0.51, respectively). However, in 2004, Santori et al18 published a report that supported the predictive value of MELD over the conventional UNOS status in short-term posttransplantation survival.

Few studies in the current literature evaluate the impact of the MELD-based allocation policy on the transplantation community. In the most comprehensive study to date, Freeman et al19 summarize the results of the first year after the implementation of MELD. Using a before-after study design, they showed a decline in the number of new registrants; an increase in the rate of deceased donor transplantation, transplantation for patients with hepatocellular carcinoma and primary sclerosing cholangitis, and combined liver-kidney transplantations; and no change in posttransplantation 3-month patient survival. They noted a trend toward decreased patient removals from waiting lists because of death or being too ill for transplantation, but these effects did not achieve statistical significance. Using a similar study design and the Organ Procurement and Transplantation Network STAR files, Kamwal et al20 found no difference in 1-year posttransplantation graft and patient survival after the implementation of MELD. Wiesner et al11 evaluated the impact of the MELD-based allocation policy on patients with hepatocellular carcinoma listed for liver transplantation. Since the implementation of MELD, the number of patients with hepatocellular carcinoma undergoing transplantation has increased, the waiting time for these patients has decreased, and the number of patients with hepatocellular carcinoma who are removed from the list because of advanced disease has decreased. Overall, the policy change has proven favorable for patients with hepatocellular carcinoma. McDiarmid et al21 evaluated the impact of MELD and the Pediatric Model for End-stage Liver Disease on the pediatric population with end-stage liver disease. They concluded that access to deceased donor organs for both children and adults has not been adversely affected by the policy change and that the overall death rate on the waiting list has been reduced for both age groups.

Although these studies provide important information regarding the impact of the MELD-based allocation policy on both pretransplantation and transplantation outcome measures, they have some limitations. Most studies focused on the impact of the policy change on posttransplantation survival. The MELD-based allocation policy was adopted with the intended goal of decreasing waiting list mortality. Thus, it seems pertinent to evaluate waiting list mortality as a primary outcome measure to determine the success of the policy change in achieving its intended goal within the liver transplantation community.
In addition, the method used in these before-after study designs fails to capture secular trends that may occur over time regardless of the effects of the allocation policy. Recall that Freeman et al.19 identified a decrease in the number of new registrants to the waiting list after the policy change. However, our study reveals remarkable seasonal variation in waiting list registration, with peaks in the summer and troughs in the winter (Figure 3). It is possible that the previous study’s findings represent a pre-policy seasonal peak followed by a post-seasonal trough. Thus, the novelty of our work is 2-fold. First, our study focuses on the impact of the MELD policy change on waiting list mortality as the primary outcome variable. Second, we assess and account for secular trends in the time series analysis to help evaluate other influences that may have affected the outcome measures.

Although we also evaluated the effect of the MELD-based allocation plan on short-term posttransplantation survival, the study focused on the impact of the policy change on its stated goal: improving access to transplantation for deceased donor recipients as determined by waiting list mortality and waiting time to transplantation. We found that the policy was associated with an immediate effect of increasing waiting list mortality by 2.2 deaths per 1000 registrants per month (Figure 1). This finding may represent the immediate removal of less-ill registrants from the list after the implementation of the MELD-based allocation policy. One other explanation involves the favorable listing of patients with hepatocellular carcinoma. These patients often have minimal or well-compensated liver disease but receive a priority score to prevent disease progression before transplantation. Thus, patients with hepatocellular carcinoma likely moved up the waiting list and received organs, whereas patients with more severe hepatic dysfunction remained on the list and died without receiving an organ. These observations are consistent with the conclusions of Wiesner et al.11

The initial increase in waiting list mortality was followed by a modest postintervention decline by 0.09 death per 1000 registrants per month. Although only statistically significant after intervention, the representation of the data shows a similar preintervention and postintervention negative slope (Figure 1). To determine the true overall effect of the intervention, it may be necessary to reevaluate these data in the future with a greater number of postintervention time points. However, the initial data suggest that the intervention was associated with a slight decline in waiting list mortality, which is consistent with the results of the work by Freeman et al.19 who report a trend toward decreased waiting list mortality and removals from the waiting list because of registrants becoming too ill to undergo transplantation.

Not surprisingly, the policy change was associated with an immediate effect of decreasing waiting list time to transplantation. With the transition in allocation policy from a system that emphasized waiting time to one that favored disease severity with a de-emphasis on patient waiting time, many less-ill registrants placed on the list for the sole purpose of “banking time” may have been removed, leading to an overall decrease in the time to transplantation for the remaining registrants. The only other study to date that identified a significant decrease in wait-

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able within the data set, and its definition did not change during the study period. Although we examined other variables that better represent patient acuity, these variables were not consistently populated. Thus, although medical condition at the time of removal may not be an ideal marker of patient acuity, it was the most appropriate variable given the limitations of the database.

We also elected to include all patients listed for transplantation during the study period, which includes candidates granted MELD exceptions and additional patients such as those with hepatocellular carcinoma. However, it is arguable that a cleaner study population would include only those patients listed based on actual MELD scores (ie, patients with acute or chronic liver failure only). If we limited the study to a smaller patient population, the power to recognize the effect of the policy change would have been less. To address this issue, we included the percentage of patients with hepatocellular carcinoma listed as a covariate in the analysis.

In solid-organ transplantation, the liver transplantation community was the first to adopt an objective score as the basis of organ allocation policy. Careful evaluation of this major change in the allocation of deceased donor livers is essential because it may direct future allocation policies. Using the interrupted time series method, our data provide more conclusive evidence that this policy had a positive impact on waiting list mortality. Because significant resources are expended in efforts to equitably allocate organs, this work provides empirical justification of this policy change.

In this study, we demonstrated findings that support the hypothesis that the implementation of the MELD-based liver allocation policy was associated with improved access to transplantation as measured by an overall decrease in waiting list mortality and waiting time to transplantation. However, unlike previous studies with before-after designs, we found no association between the policy change and the number of new registrants added to the list each month but noted a strong seasonal variation in this measure. Similar to previous studies, our data show that the policy change had no significant impact on short-term posttransplantation survival. These data and the method used are important tools in the design of future studies to further evaluate the impact of the MELD-based allocation policy on the transplantation community.

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