

Impact of Estimated Liver Volume and Liver Weight on Gender Disparity in Liver Transplantation

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Although lower Model for End-Stage Liver Disease (MELD) scores due to lower levels of serum creatinine in women might account for some of the gender disparity in liver transplantation (LT) rates, even within MELD scores, women undergo transplantation at lower rates than men. It is unclear what causes this disparity, but transplant candidate/donor liver size mismatch may be a factor. We analyzed Organ Procurement and Transplantation Network data for patients with end-stage liver disease on the waiting list. A pooled conditional logistic regression analysis was used to assess the association between gender and LT and to determine the degree to which this association was explained by lower MELD scores or liver size. In all, 28,866 patients and 424,001 person-months were included in the analysis. The median estimated liver volume (eLV) and the median estimated liver weight (eLW) were significantly lower for women versus men on the LT waiting list ($P < 0.001$). When we controlled for the region and the blood type, women were 25% less likely to undergo LT in a given month in comparison with men ($P < 0.001$). When the MELD score was included in the model, the odds ratio (OR) for gender increased to 0.84, and this suggested that 9 percentage points of the 25% gender disparity were due to the MELD score. When eLV was added to the model, there was an additional 3% increase in the OR for gender, and this suggested that transplant candidate/donor liver size mismatch was an underlying factor for the lower LT rates in women versus men (OR = 0.87, $P < 0.001$). In conclusion, lower LT rates among women on the waiting list can be explained in part by lower MELD scores, eLVs, and eLWs in comparison with men. However, at least half of the gender disparity still remains unexplained. *Liver Transpl* 19:89-95, 2013. © 2012 AASLD.

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Abbreviations: BSA, body surface area; CI, confidence interval; eLV, estimated liver volume; eLW, estimated liver weight; ESLD, end-stage liver disease; LT, liver transplantation; MELD, Model for End-Stage Liver Disease; OR, odds ratio; UNOS, United Network for Organ Sharing.

The Institutional Review Board (IRB) of the University of Maryland, Baltimore has determined that the analysis of Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) Database is not human subject research and does not need to be reviewed.

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Because of the organ shortage, donor livers should be allocated to patients with the greatest need. Before the implementation of the **Model for End-Stage Liver Disease (MELD)** in February 2002,¹ liver allocation was based on the **total waiting time on the liver transplantation (LT) list, the Child-Turcotte-Pugh score, and the hospital status.**^{2,3} In 2002, with the implementation of the MELD score (which consists of 3 objective laboratory parameters), fairness in liver allocation improved, and rates of mortality on the LT waiting list decreased.⁴ However, recent studies have revealed significantly lower LT rates and higher mortality rates in women versus men on the United Network for Organ Sharing (UNOS) LT waiting list.⁵⁻⁷

Our recent study⁶ investigating the gender disparity on the LT waiting list confirmed the results of these earlier studies. We estimated that LT rates were 25% lower in women and identified serum creatinine as a potential cause for these lower rates.⁶ Our results suggested that lower LT rates in women were in part due to the use of serum creatinine in calculating MELD scores and that this led to higher mortality rates.⁶ However, we also found that gender disparity persisted even within MELD scores.⁶ Even after accounting for MELD scores, several other reports^{7,8} have also noted lower transplant rates in women.

The explanation for the disparity in the LT rates between men and women remains unclear.⁶ The hypothesis that liver donor size mismatch contributes to lower LT rates in women versus men was previously postulated.^{6,7,9,10} Lai et al.¹⁰ included a transplant candidate's height as a surrogate marker for liver size in the multivariate model and found that women still had lower LT rates after they controlled for height. To reassess the hypothesis that liver donor size mismatch contributes to lower LT rates in women versus men, we compared men and women on the US LT waiting list with respect to LT rates and adjusted for the estimated liver size of the transplant candidate in addition to potential confounders.

PATIENTS AND METHODS

Study Population

We analyzed Organ Procurement and Transplantation Network data (via Standard Transplant Analysis and Research files) as of August 2009. We excluded the following: patients who were younger than 18 years; patients who were diagnosed with a liver disease other than end-stage liver disease (ESLD); patients who were listed on the waiting list before MELD implementation (February 27, 2002) or as an exceptional case (eg, patients with hepatocellular carcinoma who received a priority MELD score) or a status 1 case; patients who underwent living donor LT; patients who were removed from the LT waiting list for reasons other than death, transplantation, or an improved or deteriorated condition (eg, listing in error, refusal of transplant, or multiple listings); and patients who had

missing or biologically implausible height (<122 or >213 cm) and weight measurements (<34 or >227 kg) as defined by Das et al.¹¹ After these exclusions, there were 38,143 patients who fulfilled our study criteria. To avoid potential overestimations of the liver volume and weight, we also excluded patients who had more than slight ascites [in the UNOS data set, ascites was categorized as (1) absent, (2) slight, or (3) moderate] or missing data on the degree of ascites at listing (9277 patients). After the exclusion of patients who had more than slight ascites, the final study cohort had 28,866 patients.

Variables

The variables included in the analysis were as follows: patient code, waiting list registration code, registration date, last follow-up date, gender, age at registration, ethnicity/race, diagnosis, reason for removal from the waiting list, registration and updated MELD scores, exception status, UNOS region, ABO blood type, weight and height at listing, and degree of ascites at listing.

The estimated liver volume (eLV) was calculated with the formulas developed by Urata et al.,¹² Vauthey et al.,¹³ and Heinemann et al.¹⁴ The estimated liver weight (eLW) was calculated with the formulas developed by Yoshizumi et al.,¹⁵ Choukèr et al.,¹⁶ and DeLand and North¹⁷ The body surface area (BSA) was calculated with formulas developed by Du Bois and Du Bois¹⁸ and Mosteller¹⁹ for use in the calculations of eLV and eLW, respectively. Liver volume and weight estimates were included in regression models as categorical variables with 8 categories so that we could avoid making a linearity assumption.

Statistical Analysis

For the statistical analysis, we used SAS 9.2 for Windows (SAS Institute, Inc., Cary, NC)²⁰ and Minitab statistical software (Minitab, Inc., State College, PA).²¹ To assess the association between gender and LT and to determine the degree to which the association could be explained by lower MELD scores, liver volumes, or liver weights, we used a discrete survival analysis (pooled logistic regression)^{22,23} for which we reformatted the UNOS data set into 1 record per person-month of experience on the LT waiting list.⁶ Each person-month record in the data set contained information on the most recent measures of laboratory and clinical variables and the current MELD score. In addition, each record indicated whether the individual had undergone transplantation during that month. We excluded person-months in which patients were temporarily inactive on the LT waiting list. The person-month data set was analyzed by logistic regression with transplantation as the outcome. This pooled logistic regression was shown to result in approximately the same estimates and standard errors as Cox regression²⁴ with the advantage of it being easier to model the hazard, explore nonlinearities, and

include time-varying predictor variables.²³ In this analysis, we used conditional logistic regression that was conditioned on the exact MELD score and the region so that we could tightly control for these variables without making modeling assumptions. In contrast to previous analyses,^{6,10} we chose not to use a competing risk approach because our goal was not to estimate the probability that a person would receive a transplant (which can be affected by mortality rates). Rather, our goal was to determine the effects of patient characteristics on monthly transplantation rates.

To assess the degree to which various degrees of measurement error in our estimates of the liver volume could have had an impact on our adjusted estimates of the female/male transplant rate disparity, we re-estimated the gender disparity after we corrected for varying hypothetical degrees of measurement error. To do this, we used the methods of Rosner et al.²⁵ as implemented in an SAS macro developed by Logan and Spiegelman.²⁶ To use this software for specified degrees of measurement error, we simulated large hypothetical external validation sets embodying varying degrees of measurement error.

We used Wilcoxon rank-sum and chi-square tests to assess differences in quantitative and categorical variables, respectively, between women and men.

RESULTS

Clinical Characteristics of Patients With ESLD on the LT Waiting List

In all, 28,866 patients and 424,001 person-months were included in the analysis. Table 1 shows the main characteristics of our study population. The median weight, height, and BSA were significantly lower for women versus men (Table 1). The median eLV and the median eLW were significantly lower for women versus men on the LT waiting list (Table 2). The median liver volume estimated with the formula developed by Urata et al.¹² and the median liver weights estimated with the formulas developed by Yoshizumi et al.¹⁵ and Choukèr et al.¹⁶ for the study population were 1390 mL, 1539 g, and 2078 g, respectively. For each category below the median values of eLV and eLW, the proportion of women was higher than the proportion of men.

LT Rates

There were 12,444 transplants with 424,001 person-months of follow-up. The overall LT rate for patients on the waiting list was 0.35 per person-year. Women had lower LT rates than men (0.29 versus 0.39 per person-year, $P < 0.001$).

LT Rates by eLV and eLW Among Women and Men With ESLD on the LT Waiting List

Figures 1 to 3 show LT rates by the liver volume estimated with the formula developed by Urata et al.¹²

and by the liver weight estimated with the formulas developed by Yoshizumi et al.¹⁵ and Choukèr et al.,¹⁶ respectively, among women and men with ESLD on the LT waiting list. In each stratum defined by the liver size or volume, men had substantially higher transplant rates than women. The figures suggest that the gender disparity was greatest among those with the lowest liver size or volume.

Multivariate Analysis

Table 3 shows the results of fitting multivariate pooled conditional logistic models and the contributions of the MELD score, eLV, and eLW to the gender disparity. When we controlled for the region and the ABO blood type only, women had a 25% lower monthly transplant rate in comparison with men [odds ratio (OR) = 0.75, confidence interval (CI) = 0.722–0.779, $P < 0.001$]. When the MELD score was included in the model, the OR for gender increased to 0.84, and this suggested that 9 percentage points of the 25% gender disparity were due to the MELD score (OR = 0.84, CI = 0.803–0.876, $P < 0.001$). When the eLV based on the formula developed by Urata et al.¹² was added to the model as a categorical variable with 8 classes, there was an additional 3% increase in the OR for gender (OR = 0.87, CI = 0.827–0.917, $P < 0.001$), and this suggested that transplant candidate/donor liver size mismatch could be one of the factors behind the lower transplantation rates for women versus men (13 percentage points of the 25% gender disparity remained unknown). We obtained similar results when we included eLWs based on the formulas developed by Yoshizumi et al.¹⁵ (OR = 0.86, CI = 0.821–0.906, $P < 0.001$), Choukèr et al.¹⁶ (OR = 0.86, CI = 0.815–0.897, $P < 0.001$), and DeLand and North¹⁷ (OR = 0.87, CI = 0.829–0.919, $P < 0.001$) and when we included eLVs based on the formulas developed by Heinemann et al.¹⁴ (OR = 0.87, CI = 0.828–0.917, $P < 0.001$) and Vauthey et al.¹³ (OR = 0.86, CI = 0.821–0.906, $P < 0.001$) in place of the eLV based on the formula developed by Urata et al.¹² in the multivariate model controlled for the region, blood type, and MELD score.

In exploratory work requested by the reviewers of this article, we examined the effects of controlling for the individual components of the MELD score (bilirubin, international normalized ratio, and creatinine) on the transplant disparity. When bilirubin was added to a model including the region and blood type, the gender disparity became greater (OR = 0.66, $P < 0.001$). However, when creatinine or the international normalized ratio was added to the model individually, the disparity diminished (OR for each case = 0.83, $P < 0.001$).

Sensitivity Analysis to Assess the Possible Impact of Measurement Error

We assessed the degree to which these estimates might be affected by varying degrees of measurement

TABLE 1. Characteristics of 28,866 Patients With ESLD on the LT Waiting List Who Were Registered Between February 27, 2002 and August 25, 2009

Patient Characteristics	Women (n = 10,741)		Men (n = 18,125)		P Value
	Median	Quartile Range	Median	Quartile Range	
Age at listing (years)	54	11	53	10	<0.001
BSA at registration (m ²)					
Formula developed by Du Bois and Du Bois ¹⁸	1.78	0.28	2.06	0.28	<0.001
Formula developed by Mosteller ¹⁹	1.81	0.31	2.08	0.31	<0.001
Body mass index at listing (kg/m ²)	27.88	8.70	28.33	6.98	<0.001
Height at listing (cm)	162.56	10.16	177.80	10.88	<0.001
Weight at listing (kg)	73.00	23.78	88.45	24.04	<0.001
MELD score at listing	14	8	15	8	<0.001

Patient Characteristics	Women (n = 10,741)		Men (n = 18,125)		P Value
	n	%	n	%	
Race/ethnicity					<0.001
White	7497	70	13,387	74	
Black	942	9	1275	7	
Hispanic	1851	17	2779	15	
Asian	315	3	498	3	
Other	136	1	186	1	
Etiology of cirrhosis					<0.001
Autoimmune hepatitis	926	9	320	2	
Cryptogenic	1475	14	1689	9	
Alcohol	1388	13	4282	24	
Hepatitis B	181	2	667	4	
Hepatitis C	4147	39	9621	53	
Nonalcoholic fatty liver disease	946	9	819	5	
Primary biliary cirrhosis	1354	13	209	1	
Primary sclerosing cholangitis	16	0	32	0	
Other	308	3	486	3	
ABO blood type					0.01
A	3860	36	6796	38	
AB	399	4	736	4	
B	1327	12	2180	12	
O	5155	48	8413	46	
UNOS region					<0.001
1	342	3	767	4	
2	1043	10	2064	11	
3	1287	12	2229	12	
4	1543	14	2030	11	
5	2039	19	3345	18	
6	330	3	607	3	
7	952	9	1512	8	
8	693	6	1111	6	
9	854	8	1458	8	
10	871	8	1365	8	
11	787	7	1637	9	

error in our estimates of liver volume. To perform this analysis, we started by refitting the model and treating the liver volume as continuous. With that model, adjusting for the MELD score, region, blood type and eLV, we found a 15% gender disparity. If the correlation between eLV and the true liver volume was 80%, the estimate of the gender disparity corrected for the measurement error was 13%. If the correlation between eLV and the true liver volume

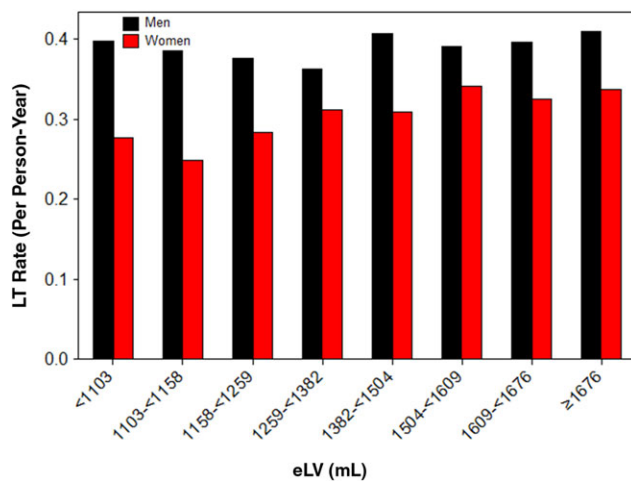
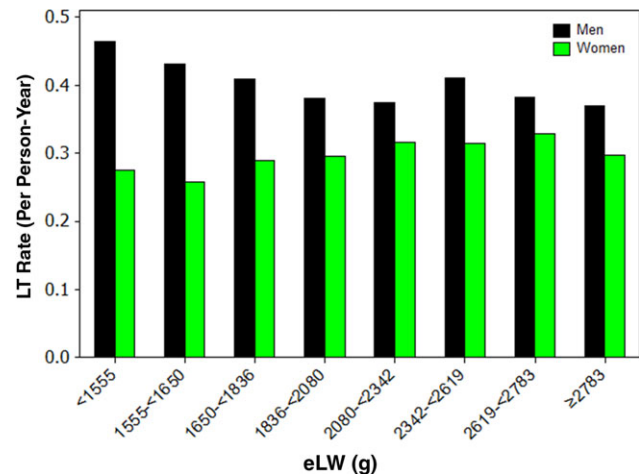
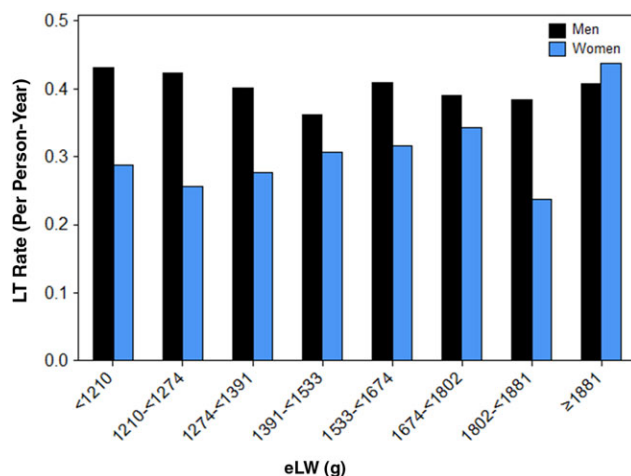
was poor (60%), the corrected estimate of the disparity was 9%.

DISCUSSION

The hypothesis that liver size mismatch between the LT candidate and the donor could explain the lower transplantation rates in women versus men on the LT waiting list was previously postulated by other

TABLE 2. eLV and eLW Values for Patients With ESLD on the LT Waiting List

	Women (n = 10,741)		Men (n = 18,125)		P Value
	Median	Quartile Range	Median	Quartile Range	
eLV based on formula developed by Urata et al. ¹² (mL)	1259.36	195.44	1455.46	197.44	<0.001
eLW based on formula developed by Yoshizumi et al. ¹⁵ (g)	1398.91	241.45	1609.29	237.98	<0.001
eLW based on formula developed by Choukèr et al. ¹⁶ (g)	1868.74	411.50	2199.45	476.35	<0.001
eLV based on formula developed by Vauthey et al. ¹³ (cm ³)	1501.97	396.35	1847.32	390.66	<0.001
eLV based on formula developed by Heinemann et al. ¹⁴ (mL)	1563.78	296.90	1861.66	299.94	<0.001
eLW based on formula developed by DeLand and North ¹⁷ (kg)	1.60	0.28	1.88	0.29	<0.001

Figure 1. LT rates by the liver volume estimated with the formula developed by Urata et al.¹² among women and men with ESLD on the LT waiting list.Figure 3. LT rates by the liver weight estimated with the formula developed by Choukèr et al.¹⁶ among women and men with ESLD on the LT waiting list.Figure 2. LT rates by the liver weight estimated with the formula developed by Yoshizumi et al.¹⁵ among women and men with ESLD on the LT waiting list.

authors.^{6,7,9,10} Our results suggest that this is true to some extent. However, the contribution of the liver size to the gender disparity appears relatively small and does not explain a large portion of the disparity.

In this study, our goal was not to estimate the probability that a person would receive a transplant but rather to determine the effects of patient characteristics on monthly transplantation rates. After taking into account the region and the blood type, we observed that the monthly transplant rate was 25% lower for women than men with ESLD on the LT waiting list. Lower MELD scores explained part of this disparity because after we controlled for the MELD score, the disparity was reduced to 16%. Finally, after adjustments for the eLV and eLW of transplant candidates, LT rates were still 13% lower in women versus men. Our results are also consistent with those of Lai et al.,¹⁰ who, using a different analysis, found that women had a 12% lower LT rate after they controlled for the MELD score and height.

Although our analysis shows that lower LT rates in women are in part due to liver size in addition to the MELD score, an explanation for half of the 25% gender disparity still remains unclear. One can speculate that age or the etiology of cirrhosis may play a role in this gender disparity, but once a transplant candidate is registered on the LT waiting list with a designated MELD score, demographic or clinical characteristics such as age, the etiology of cirrhosis, and race do not play any role in liver allocation. We would

TABLE 3. Factors by which the LT Rates are Lower in Women than Men, Controlling for other Variables Using Pooled Logistic Regression

Controlled Variables	OR for LT in Females	
	Versus Males	P Value
Gender + UNOS region + blood type	0.75	<0.001
Gender + UNOS region + blood type + MELD score	0.84	<0.001
Gender + UNOS region + blood type + MELD score + eLV (mL)*	0.87	<0.001
Gender + UNOS region + blood type + MELD score + eLW (g) [†]	0.86	<0.001
Gender + UNOS region + blood type + MELD score + eLW (g) [‡]	0.86	<0.001
Gender + UNOS region + blood type + MELD score + eLV (mL) [§]	0.87	<0.001
Gender + UNOS region + blood type + MELD score + eLV (mL)	0.86	<0.001
Gender + UNOS region + blood type + MELD score + eLW (kg) [¶]	0.87	<0.001

*Based on the formula developed by Urata et al.¹²

[†]Based on the formula developed by Yoshizumi et al.¹⁵

[‡]Based on the formula developed by Choukèr et al.¹⁶

[§]Based on the formula developed by Heinemann et al.¹⁴

^{||}Based on the formula developed by Vauthey et al.¹³

[¶]Based on the formula developed by DeLand and North.¹⁷

like to emphasize that clinical characteristics (eg, age, race, and diagnosis) may play a role in mortality on the LT waiting list, but they should have no effect on LT allocation because in the United States, the allocation of livers from deceased donors is dependent only on the MELD score, ABO blood type, and UNOS region. Therefore, in the multivariate analysis, we did not control for variables other than the MELD score, ABO blood type, UNOS region, and liver size.

Because information on the actual size of the transplant candidates' livers was not available in the database, we estimated the liver size with several previously published formulas. The estimates from these formulas resulted in similar liver sizes and outcomes (Tables 2 and 3). Because these formulas required the transplant candidate's body weight or BSA to estimate the liver volume and weight, we excluded transplant candidates who had more than slight ascites or missing data on ascites to prevent overestimations of the liver volume and weight. This may have resulted in a selection bias. However, when we repeated our multivariate analysis without excluding those with more than slight ascites or missing data on ascites, we obtained similar results.

Our study had limitations because it was a retrospective analysis. Because the UNOS database did not have information on the actual liver size, we estimated the liver weights and volumes with previously published formulas. Using these formulas, we may have underestimated or overestimated the sizes of livers. However, our sensitivity analysis provides some assurance that the observed disparity was not simply due to liver size estimation errors.

Each of these formulas for liver size and weight has strengths and limitations. The formula developed by Urata et al.¹² was derived from a relatively small number of Japanese subjects, the majority of whom were pediatric. The actual liver volume was measured by computed tomography.¹² The greatest strength of this

formula was that among the 6 estimating formulas, it had the highest R^2 value (the multivariate model for the liver volume explained 96% of the change in the actual liver volume).¹² The formula developed by Yoshizumi et al.¹⁵ had the largest sample size and was derived from a US population of cadaveric liver donors with a large range of ages. The formula developed by Choukèr et al.¹⁶ was derived from autopsies and was the only one taking into account age and gender for subjects between the ages of 16 and 50 years and age for subjects between the ages of 51 and 70 years in addition to weight. Moreover, in the study by Choukèr et al.,¹⁶ there was no information about whether they excluded cases with heart failure or shock; livers obtained from autopsies may be heavier than the actual liver weight because of hepatic congestion if there is any congestive heart failure or shock before death. In fact, the highest median liver weight in our study was obtained with the formula derived by Choukèr et al.¹⁶ (Table 2 and Fig. 3). Heinemann et al.¹⁴ derived their estimating formula from a large number of autopsies of Caucasian subjects. However, the R^2 value of their formula was small.¹⁴ Vauthey et al.¹³ developed a formula by measuring the liver volume with computed tomography in North American and European subjects, and they excluded Asians and African Americans. In the study conducted by DeLand and North,¹⁷ there was no information about whether the weight of the gallbladder and hepatic attachments was excluded when the liver weight was measured, and R^2 of the formula was not reported. As mentioned, all these estimating formulas differed in their populations, measurement techniques, and inclusion and exclusion criteria.¹²⁻¹⁷ In order to minimize the potential bias that could occur because of these variations in the formulas, we estimated the liver weight and volume with not just 1 formula but with 6 independent estimating formulas. We repeated our multivariate analysis by using these

different formulas to reduce the bias in our results. Each of these formulas resulted in similar outcomes.

Because information on transplant candidates' weights and heights was not available for the last follow-up on the LT waiting list in the data set, we estimated the liver size on the basis of the weight, height, and degree of ascites available at registration on the LT waiting list. Although LT candidates' weight and ascites are dynamic variables and may change during the stay on the waiting list, these changes should have had a minor effect on the estimation of liver size because we excluded patients who had more than slight ascites or missing data on ascites.

To our knowledge, this is the first study showing that the liver size of LT candidates contributes to the disparity of lower LT rates among women on the LT waiting list. We have shown that women have significantly lower median eLV and eLW values than men on the LT waiting list and are significantly less likely to undergo LT than men. Lower transplantation rates among women on the LT waiting list can be explained in part by lower MELD scores and lower eLV and eLW values in comparison with men. As suggested by Myers et al.,⁸ this portion of the transplant disparity attributed to the MELD score might be diminished if the MELD score were based on the estimated glomerular filtration rate rather than serum creatinine. Finally, even after accounting for the MELD score and estimated liver size, we have found that approximately half of the 25% gender disparity remains unexplained.

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