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Effect of the lung allocation score on lung transplantation in the United States

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BACKGROUND: On May 4, 2005, the system for allocation of deceased donor lungs for transplant in the United States changed from allocation based on waiting time to allocation based on the lung allocation score (LAS). We sought to determine the effect of the LAS on lung transplantation in the United States.
METHODS: Organ Procurement and Transplantation Network data on listed and transplanted patients were analyzed for 5 calendar years before implementation of the LAS (2000–2004), and compared with data from 6 calendar years after implementation (2006–2011). Counts were compared between eras using the Wilcoxon rank sum test. The rates of transplant increase within each era were compared using an *F*-test. Survival rates computed using the Kaplan-Meier method were compared using the log-rank test.
RESULTS: After introduction of the LAS, waitlist deaths decreased significantly, from 500/year to 300/year; the number of lung transplants increased, with double the annual increase in rate of lung transplants, despite no increase in donors; the distribution of recipient diagnoses changed dramatically, with significantly more patients with fibrotic lung disease receiving transplants; age of recipients increased significantly; and 1-year survival had a small but significant increase.
CONCLUSIONS: Allocating lungs for transplant based on urgency and benefit instead of waiting time was associated with fewer waitlist deaths, more transplants performed, and a change in distribution of recipient diagnoses to patients more likely to die on the waiting list.
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Lung transplant (LTX) is accepted therapy to palliate patients with end-stage lung diseases. However, LTX is severely constrained by the shortage of brain-dead organ donors and suitable lung donors in particular. This situation has resulted in strict listing guidelines[1] and focus on organ allocation policies. In 1999, the U.S. Department of Health and Human Services released the Final Rule on organ allocation,[2] which required the Organ Procurement and Transplantation Network (OPTN) to emphasize broader sharing of organs, reduce waiting time as an allocation criterion, and create equitable organ allocation systems using objective medical criteria and medical urgency. The OPTN is the network that links the organizations of the solid-organ donation and transplantation system in the United States, including transplant centers, organ procurement organizations, and histocompatibility laboratories. The United Network for Organ Sharing is a private non-profit membership organization that is designated as the OPTN under contract with the U.S. Department of Health and Human Services; the United Network for Organ Sharing has held the OPTN contract since its inception in 1986.A report commissioned from the Institute of Medicine agreed that organ allocation should be based on measures of medical urgency, while avoiding futile transplants, and should

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minimize the effect of waiting time; it also encouraged broader geographic sharing in organ allocation.[3] In 1998, the Lung Allocation Subcommittee of the OPTN Thoracic Organ Transplantation Committee was created to evaluate the U.S. lung allocation system and make recommendations to comply with the Final Rule.

Based on analyses by the OPTN and the Scientific Registry for Transplant Recipients, the Lung Allocation Subcommittee recommended a new allocation system for transplant candidates $\geq$12 years old, changing from allocation of donor lungs based on waiting time to allocation based on a lung allocation score (LAS). The LAS is calculated using pre-transplant clinical diagnostic factors predictive of survival during the following year on the waiting list without a transplant as well as survival during the first year after a transplant.[4] Development of the LAS and the rationale for using it in recipients $\geq$12 years old are reviewed elsewhere.[5,6] The policy was approved by the OPTN Board of Directors in 2004 and implemented in May 2005.

In this article, we show the effect of the LAS on LTX in the United States by comparing outcomes of patients on the waiting list and after transplantation for 5 years before introduction of the LAS with patients for 6 years after LAS implementation. Although the numbers reported here are published every year in annual reports of the Scientific Registry for Transplant Recipients,[7–9] this article analyzes trends over time and demonstrates the statistical and practical significance of changes observed in LTX practice associated with introduction of the LAS over more than a decade. We do not offer opinions about the pros and cons of these observed changes.

Methods

Tabulations are based on OPTN data as of March 8, 2013. The cohorts analyzed included LTX candidates ever waiting, transplants performed, and deceased donors recovered for the years 2000–2011. Waitlist and post-LTX mortality data were supplemented from the Social Security Death Master File data. Restrictions on complete public release of the Social Security Death Master File since November 2011 may result in an underestimate of mortality for November and December 2011. This restriction also is the basis for not including data from 2012 or later.

Diagnoses were grouped according to the LAS classification, with some exceptions: the addition of "other," which included patients with sarcoidosis, autoimmune diseases, and a small group of unusual diagnoses not typically associated with pulmonary fibrosis, and retransplant as a separate group. Details of diagnostic groups and modifications are included in the Supplementary materials (available online at jhltonline.org). For this analysis, patients were assigned to emphysema (chronic obstructive pulmonary disease [COPD]), pulmonary hypertension, cystic fibrosis, restrictive lung diseases (fibrotic lung disease), other, and retransplant.

Counts were compared between eras using the non-parametric Wilcoxon rank sum test, using the ranks of values, rather than the values themselves. Because only a limited number of ranks were compared, and the patterns of ranks were the same in several instances with regard to the number of years with higher (or lower) ranks before the LAS compared with after the introduction of the LAS, the p-values were sometimes identical. Increased transplant rates within each era were compared by the F-test. Survival rates computed using the Kaplan-Meier method were compared using the log-rank test. Patient survival was censored at the earlier date of either last reported follow-up or retransplant. Because the system changed suddenly on May 4, 2005, data from 2005 were affected by both allocation systems and so are not shown in most figures for better comparison of pre-LAS and post-LAS cohorts.

Results

The absolute number of LTX procedures was increasing during the 5 years before introduction of the LAS. However, there was a significant 20% increase in the number of LTX procedures performed after introduction of the LAS (p = 0.0062). Moreover, the annual rate of LTX procedures increased significantly, from 45/year to 91/year (Figure 1A). This increase was not due to a corresponding increase in brain-dead organ donors (Figure 1B). Introduction of the LAS coincided with a dramatic reduction in living-donor bilateral lobe transplants (Figure 1C). This procedure is

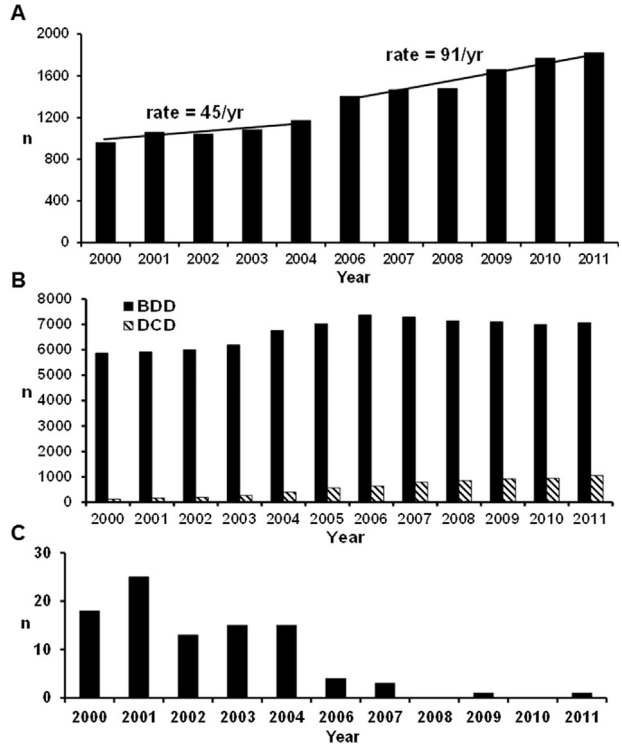

Figure 1 Number of lung transplants before (2000–2004) and after (2006–2011) introduction of the lung allocation score (LAS). (A) Lung transplant procedures. The absolute number of lung transplants increased significantly (p = 0.0062, Wilcoxon test). The annual increase in lung transplants doubled from a rate of approximately 45/year before the LAS to 91/year after the introduction of the LAS (p = 0.0228, F-test). Note: Data for 2005 are not shown. (B) Total brain-dead organ donors (BDD) and donation after cardiac death donors (DCDs) for 2000–2011. The increase in lung transplants after introduction of the LAS was not related to an increase in organ donors. (C) Bilateral lobe transplants from 2 living donors was uncommon before 2005, but was virtually eliminated after introduction of the LAS in 2005. Note: Data for 2005 are not shown.