Local Allocation of Lung Donors Results in Transplanting Lungs in Lower Priority Transplant Recipients

Mark J. Russo, MD, MS,* David Meltzer, MD, PhD, Aurelie Merlo, AB, Elizabeth Johnson, MA, Nazly M. Shariati, MD, MS, Joshua R. Sonett, MD, and Robert Gibbons, PhD

The Harvey and Georgina Weinstein National Heart and Lung Transplant Center, Barnabas Heart Institute, Newark-Beth Israel Medical Center, Newark, New Jersey; Cardiovascular Clinical Research Center, Barnabas Heart Institute, Newark, New Jersey; Center for Health and the Social Sciences, University of Chicago, Chicago, Illinois; Division of Cardiothoracic Surgery, Department of Surgery, College of Physicians and Surgeons, Columbia University, New York, New York; and Center for Health Statistics, University of Chicago, Chicago, Illinois

Background. **Under the current lung allocation system, if organs are accepted for a candidate within the local donor service area (DSA), they are never offered to candidates at the broader *regional* level who are potentially more severely ill, even if the nonlocal candidate has a higher lung allocation score (LAS). The purpose of this study was to determine the frequency with which organs were allocated to a local lung recipient while a blood group–matched and size-matched candidate with a higher LAS existed in the same region.**

Methods. **United Network for Organ Sharing (UNOS) provided deidentified patient-level data. The study population included all locally allocated organs for double-lung transplants (DLTs) performed in 2009 in the United States (n = 580). All occurrences of an ABO blood group–matched, height-matched (± 10 cm), double-lung candidate in the same region, with a higher LAS than the local candidate who actually received the organs, were calculated; these occurrences were termed *events*.**

Results. **In 2009, 3,454 events occurred when a local DLT recipient candidate received a DLT while a DLT candidate in the same region had a higher LAS. With a mean of 5.96 events per transplant, this impacted 480 (82.8%) of the 580 DLTs. Further, 555 (16.1%) of these events involved 1 (or more) of the 185 regional candidates who ultimately did not receive transplants and died while on the waiting list.**

Conclusions. **This analysis suggests that the locally based lung allocation system results in a high frequency of events whereby an organ is allocated to a lower-priority candidate while an appropriately matched higher priority candidate exists regionally.**

(Ann Thorac Surg 2013;95:1231–5)

Given the disparity between potential recipients and available organs, efficient methods of organ allocation are needed to achieve maximal benefit from available organs. Our group has demonstrated in previous studies [1–4] that despite changes in the current lung allocation system, the following conditions exist: (1) high-priority lung transplantation candidates with lung allocation scores (LASs) of 75+ continue to die at high rates while on the transplant waiting list; (2) concurrently, more than four-fifths of lungs are allocated to low-priority candidates with an LAS less than 50; and (3) these low-priority recipients receive little net survival benefit from transplantation. These findings suggest that additional changes are needed to address the inefficiencies in the current lung allocation system and to maximize the benefit of organs available for transplantation.

More than a decade ago, the US Department of Health and Human Services (DHHS) issued the “Final Rule,” which was intended to ensure that “allocation of scarce organs be based on common medical criteria, not accidents of geography” [5]. In 1998, the DHHS and Institute of Medicine (IOM) assembled an expert panel to assess the potential impact of the Final Rule on organ allocation in liver transplantation. The IOM analysis, which was completed in July 1999, concluded that “broader sharing of organs led to an overall increase in the rate at which the most severely ill patients were transplanted and a concomitant decrease in the excess transplantation of the least severely ill patients, without increasing pretransplantation mortality” [6]. More recently, in 2005, the Organ Procurement and Transplantation Network (OPTN) Lung Allocation Subcommittee recommended changes to the lung allocation policies “to minimize the effects of geography on waitlist outcome,” in an effort to reduce waitlist mortality [7]. Despite the introduction of

Accepted for publication Nov 27, 2012.

*Recipient of The Society of Thoracic Surgeons 2012 President’s Award.

Presented at the Forty-eighth Annual Meeting of The Society of Thoracic Surgeons, Fort Lauderdale, FL, Jan 28–Feb 1, 2012.

Address correspondence to Mark Russo, The Harvey and Georgina Weinstein National Heart and Lung Transplant Center, Barnabas Heart Institute, Newark Beth Israel Medical Center 201 Lyons Avenue, Newark, NJ 07112; e-mail: mr2143@gmail.com.

Published by Elsevier Inc

0003-4975/$36.00
http://dx.doi.org/10.1016/j.athoracsur.2012.11.070

Abbreviations and Acronyms

- DHHS = Department of Health and Human Services
- dLAS = delta lung allocation score
- DLT = double-lung transplant
- DSA = donor service area
- IOM = Institute of Medicine
- LAS = lung allocation score
- OPO = Organ Procurement Organization
- OPTN = Organ Procurement and Transplantation Network
- UNOS = United Network for Organ Sharing

the Final Rule, the findings of the IOM panel, and the recommendations of the OPTN, lung allocation remains a locally based system.

Under the locally based system, organs are initially offered only to the subset of appropriately matched lung transplantation candidates (based on blood group and size) within the donor's local donor service area (DSA). As a result, if an available organ is first accepted for a candidate within the local DSA, it is never offered at the broader regional or national level to candidates who are potentially more severely ill, even if the regional or national candidate has a much higher priority score.

The purpose of this study was to determine the frequency with which organs were allocated to a local lung recipient while there existed a blood group–matched, size-matched candidate with a higher LAS in the same region. We hypothesized that organs are frequently allocated to local candidates with lower LASs while regional candidates with higher LASs continue to die while awaiting transplantation.

Material and Methods

Data Collection

Use of data in this analysis was approved by the University of Chicago's Institutional Review Board (IRB) and is consistent with the regulations of the UNOS Data Use Agreement. The individual consent requirement was waived by the University of Chicago's IRB for this study because of the retroactive and deidentified nature of the data. The Standard Transplant Analysis and Research data set was provided by the United Network for Organ Sharing (UNOS (data source 01052011-6). UNOS provided deidentified patient-level data for all lung transplantation candidates and recipients in the United States. The data set contains information collected from the UNet^{SM} database forms, including the Transplant Candidate Registration Form, the Transplant Recipient Registration Form, and the Transplant Recipient Follow-up Form. These data sets are the basis for the UNOS Thoracic Registry.

This data set contains nearly 500 fields to characterize candidate/recipient and donor information, including demographics (eg, age, race, and sex), social history, and clinical information (eg, blood type, measures of lung function and hemodynamic measures, medical and surgical history, serologic test results, and severity of comorbid illness).

With special permission, UNOS provided supplemental data, including candidate listing/transplant center and candidate and donor organ procurement organization (OPO). In addition, UNOS provided data regarding interval changes in candidates' LAS while on the waiting list; an LAS for each candidate is typically provided for each day on the waiting list. This supplemental data totaled 2.5 million observations.

Study Population

The study group included lung transplant recipients who had an LAS, were aged $\geq$ 12 years, and received a double lung transplant (DLT) in 2009 (N = 580). Recipients who underwent simultaneous transplantation of another organ (n = 36) and those with missing LAS data (n = 15) were excluded from the analysis.

Data Analysis

All data were analyzed using the statistical software package, Stata 11 MP (Stata Corp, College Station, TX). Categorical variables were reported as counts and percentages. Continuous variables were reported as means.

Definitions

EVENT: All occurrences of an ABO blood group–matched, height-matched ($\pm$ 10 cm), double-lung candidate in the same region with a higher LAS than the local candidate who actually received the organs.

DELTA LAS (DLAS): The difference between the LAS of the regional candidate who was bypassed, and the LAS of the candidate who actually received the organ.

PRIMARY OUTCOME: All occurrences of an ABO blood group–matched, height-matched ($\pm$ 10 cm), double-lung candidate in the same region with a higher LAS than the local candidate who actually received the organs.

SECONDARY OUTCOMES: All occurrences of an ABO blood group–matched, height-matched ($\pm$ 10 cm), double-lung candidate in the same region with an LAS 10, 25, or 50 points higher than the local candidate who actually received the organs. In addition, the number of events in which the candidate ultimately died on the waiting list was determined, as well as the number of discrete candidates bypassed who died.

Results

Study Population

In 2009, there were 580 locally allocated organs for DLTs in the United States. The mean LAS of transplanted local DLT recipients in this study was 42.5 $\pm$ 14.6.

Events

In 2009, 3,454 events occurred whereby a local DLT recipient candidate received a DLT while there was a DLT candidate in the same region with a higher LAS. With a mean of 5.96 events per transplant, this impacted

Table 1. Study Group: Locally Allocated Double-Lungs[a]

Variable	Total Double-Lung Transplants Analyzed	No. of Events	Mean Events Per Transplant	No. of Transplants Involved	% of Transplants Involved	No. of Patients	No. of Patient Deaths	% of Patients Who Died
dLAS > 0	580	3,454	5.96	480	82.8	1,193	185	15.5
dLAS > 10	580	828	1.43	320	55.2	333	91	27.3
dLAS > 25	580	250	0.43	170	29.3	111	41	36.9
dLAS > 50	580	63	0.11	48	8.3	41	19	46.3

[a] Analysis of all 580 locally allocated organs for double-lung transplantation in 2009 in the United States based on ABO blood group–matched, height-matched (± 10 cm), double-lung candidates in the same region who had a higher LAS than the local candidate who actually received the transplant.

dLAS = delta lung allocation score; LAS = lung allocation score.

480 (82.8%) of the 580 DLTs. Among these, 828 had a dLAS greater than 10, 250 had a dLAS greater than 25, and 63 had a dLAS greater than 50.

Differences in LAS of greater than 10, greater than 25, and greater than 50 affected 320 (55.2%) transplants, 170 transplants (29.31%), and 48 transplants (8.28%), respectively. The mean number of events per transplant with differences in LAS of greater than 10, greater than 25, and greater than 50 were 1.43, 0.43, and 0.11, respectively (Table 1).

Related Deaths

In total, 555 (16.1%) of these events involved a regional candidate who did not receive a transplant and ultimately died while on the waiting list, including 185 separate candidates. Among these deaths, 91 were in regional candidates with a dLAS greater than 10, 41 in candidates with a dLAS greater than 25, and 19 in candidates with a dLAS greater than 50 (Table 1).

Comment

This analysis suggests that organs are commonly allocated to local candidates with a lower LAS while regional candidates with a higher LAS continue to wait and/or die without the benefit of transplantation. The study further reveals that 185 separate candidates who were bypassed in favor of local candidates with a lower LAS ultimately died while waiting.

Waiting List Outcomes

In previous studies [1–4], our group demonstrated that despite recent changes in the lung allocation system, inefficiencies persist in the current system. First, since the initiation of the LAS in 2005, more than 80% of donor lungs were allocated to low-priority candidates (LAS < 50). Differences in LAS have a clinically meaningful relationship with survival on the waiting list in the absence of transplantation. Based on our previous analysis of survival on the waiting list in the absence of transplantation, waiting list survival among patients with an LAS less than 50 is approximately 4 years, those with an LAS 50 to 74 is approximately 6 months, and those with an LAS 75+ is less than 30 days.

These findings are particularly troublesome because low-priority candidates rarely die while awaiting transplantation. In fact, in a previous study, our group demonstrated that at 1 year follow-up, less than 10% of candidates with an LAS less than 50 die on the waiting list. More significantly, low-priority candidates appear to receive little or no net survival benefit from transplantation [2, 9]. Based on these findings, we concluded that additional changes are needed to address the inefficiencies of the current lung allocation system and to maximize the benefit of organs available for transplantation. These inefficiencies may result, in part, because of the locally based allocation system, which results in a higher allocation of organs to candidates with less urgent needs.

Local Geographic Units

The local geographic units for lung transplantation consist of 58 DSAs in the United States and Puerto Rico. The OPOs are responsible for obtaining and allocating organs for transplantation within the DSAs. DSAs and OPOs lack standardization. Most notably, the populations of DSAs differ by nearly 20-fold, ranging from 1.3 million to 18.7 million, and organ recovery practices vary significantly across OPOs [8]. Therefore, it should not be surprising that there is wide variability across OPOs in performance measures, including donor consent rates, conversion rate of candidates to organ donors, organs procured per donor, and candidate wait times [8].

Limitations

This study has several limitations. First, patient registries often suffer from data entry variability. However fields contained within this database were generally well populated with a 95% to 99% data entry rate for the majority of variables. Second, although the UNOS reporting system provided variable definitions in data guidelines, definitions may still differ by center. Third, this analysis was retrospective. Although the data analysis supports associations between variables and outcomes, causal relationships cannot be determined. Fourth, information regarding why organs were declined for a candidate was not available. Fifth, some clinicians and policymakers have expressed concern that broader organ sharing will lead to lower donation rates because the potential donors may prefer to have members of their local community benefit from their donation. With the available data, this study cannot evaluate the impact of broader organ sharing on donation rates. However in its evaluation of this issue, the IOM panel found “little or no evidence to support the assertion that people would decline to donate . . . if they knew a donated organ would be used outside the donor's immediate geographic area" [6]. Sixth, to simplify the analysis, DSAs and regions, rather than distances, were used to define geography. In the UNOS data, there was not sufficient demographic information related to the donor hospital to reliably calculate distance between donor and transplantation center. Finally, because this study considers only double-lung candidates, does not consider national matches, and does not allow for blood groups to be crossed, it likely underestimates the frequency of these events and the number of lives lost.

Implications and Future Studies

With the current system of prioritizing local candidates over potentially higher priority regional candidates, this study suggests that high-priority lung candidates are dying unnecessarily while waiting for donor lungs. Such findings are even more troubling because it appears that lower priority candidates receive little or no net survival benefit from transplantation [2]. Combined with the results of the IOM panel researching broader organ allocation in liver transplantation, these studies suggest that organ sharing over a broader geographic area would increase the net survival benefit of lung transplantation.

Two potential improvements to the current policy include (1) allocating organs over a larger geographic area (eg, 250 or 500 miles) based on LAS, rather than limiting priority to local candidates or (2) using a system similar to the system for heart transplantation in which organs are preferentially allocated to high-priority (eg, LAS 75+) candidates locally, then high-priority candidates over a broader geographic area (eg, regionally or over a 250–500 mile radius), then intermediate-priority (eg, LAS 50–74) candidates locally, then intermediate-priority candidates over a broader geographic region, then low-priority (eg, LAS $<$ 50) candidates locally, and then low-priority candidates over a broader geographic region.

Our group is undertaking further studies to replicate the analysis performed by the IOM group to test the central hypothesis that organ sharing over broader geographic areas would result in better allocation of organs as measured by higher rates of organ allocation to higher priority candidates, improved survival on the waiting list among lung transplantation candidates, and an increased net benefit of transplantation.

Conclusions

Findings from this analysis suggest that the locally based allocation system results in a high frequency of events whereby an organ is allocated to a lower priority candidate while an appropriately matched higher priority candidate exists regionally. This may result unnecessarily in the death of higher priority candidates, thus diminishing waiting list outcomes and the net benefit of transplantation. Additional changes to the lung allocation system are needed to maximize the currently available pool of organs for transplantation.

This work was supported by the Thoracic Surgery Foundation for Research and Education.

References

1. Gibbons RD, Duan N, Meltzer D, et al. Institute of Medicine Committee. Waiting for organ transplantation: results of an analysis by an Institute of Medicine Committee. Biostatistics 2003; 4:207–22.
2. Russo MJ, Hong KN, Iribarne A, Gelijns A, Sonett JR. Does lung allocation score predict net benefit from lung transplantation. J Thorac Cardiovasc Surg 2011;141:1270–7.
3. Iribarne A, Sonett JR, Easterwood R, et al. Distribution of donor lungs in the United States: a case for broader geographic sharing. Presented at the 37th Annual Meeting of the Western Thoracic Surgical Association, Colorado Springs, CO. *http://www.westernthoracic.org/Abstracts/2011/CF16.cgi*. Accessed January 18, 2013.
4. Iribarne A, Russo MJ, Davies RR, et. al. Despite Decreased wait-list times for lung transplantation, lung allocation scores continue to increase. Chest 2009;135:923–8.
5. Organ Procurement and Transplantation Network. Health Resources and Services Administration, HHS. Final Rule. Fed Regist 1999;64:56650–1.
6. Institute of Medicine. Organ procurement and transplantation: assessing current policies and the potential impact of the DHHS final rule (1999). Washington, DC: National Academy Press. Available at: http://www.nap.edu/openbook.php?isbn=030906578X. Accessed December 14, 2012.
7. Egan T, Murray, Bustami RT. Development of the new lung allocation system. Am J Transplant 2006;6:1212–27.
8. Eason JD. Donor Service Area (DSA) as the first unit of allocation. Bethesda, MD: US Department of Health and Human Services Health Resources and Services Administration, August 2010. Available at: http://optn.transplant.hrsa.gov/SharedContentDocuments/Session7A_Eason.pdf. Accessed December 14,2012.

DISCUSSION

DR THOMAS EGAN (Chapel Hill, NC): Congratulations on finally providing some data. You'll see when I get up and talk about a national allocation system that there is virtually no data in the literature to argue in favor of more widespread distribution.

I was curious why you used UNOS regions, which are just as foolish as OPOs in some respects because of the huge difference in size of the regions.

DR RUSSO: Sure. It's simple. There was essentially 2 ways to do this, 1 was to use the regions, the other way would be to use a mapping program that would actually map where the candidates were. So what you're basically suggesting is, should it be a 200- or 500-mile radius around which the organs are allocated, and I happen to agree with you that the boundaries don't make any sense, as we showed in our clinical scenario, where the patient was 20 miles from the donor hospital but outside of the local DSA. It was basically to simplify the analysis in short.

DR DAVID MASON (Cleveland, OH): I thought that was really a fascinating talk and a lot of work to try to get to an answer, and sometimes the answer takes a lot of complicated work. Honestly, I got lost a bit along the way.

What is your recommendation? Do you have an idea of what changes you would like to see? It seems like there are always going to be lines drawn. There is an eastern time zone, there's a central time zone, and you live across the time zone, your clock is different, unfortunately. It seems there will need to be certain lines that need to be drawn.

DR RUSSO: Well, I think that heart transplant offers a reasonable model to do this where patients who are 1A and 1B are allocated first. So whether the patient is regional or local, it goes to the highest priority patient—well, I'm sorry, it goes to the 1A or 1B local. If that doesn't exist, then it goes to the 1A or 1B regional, and then it only goes to a 2 local if there is no 1A or 1B within a 500-mile radius, so it's not within the regions. I think that that's a reasonable mechanism. I think the way that you would adopt that to LAS is to define ranges, and I don't know if these are the best, but the most simplistic ranges would be to say between 25 and 50, between 50 and 75, and between 75 and 100.

Actually in some of the previous work that we've done, we've been able to show that if you look at the patients who are between LAS of 25 and 50, their survival is generally estimated, in the absence of transplant, in terms of years; patients between 50 and 75, it's months, and then patients greater than 75, it's weeks to days. So there is actually some clinical data I think to support that, but I think that having an LAS range that's analogous to the 1A, 1B, 2 system I think makes a lot of sense.

DR STEPHEN CASSIVI (Rochester, MN): I'm just rising to congratulate you on also putting some data to a problem that we all know is there. I mean, we face different geographic boundaries at election time, but more blatantly, and it affects probably more lives when we face them at the time of transplant. It's just ridiculous that the geographic or political boundaries of one state versus another means that one person gets denied an organ that would likely go to them if it was in a proper allocation system.

I would argue to you that we currently have computer systems—and you've clearly got some matrices there that are quite complex to do the research you've done—but we've got computers now that can easily map out 250-mile or 300-mile or 500-mile radii that at the time of allocation could be instituted, and maybe in the era of an evolving ex vivo, or whatever, perfusion model, we can extend the ischemic time such that we can really wipe out some of these boundaries. It would be appropriate to get the right patients transplanted at the right time.

DR RUSSO: Two comments on that. In some of our previous work we showed that probably about, I think it's 83% of patients who are transplanted have LAS scores of less than 50, whereas a very small percentage of patients with much higher scores are transplanted. That would be fine if the higher score patients weren't dying on the list, but they in fact are.

The second thing that I would say is, I think that it would be great if we could have better preservation systems, but quite honestly, an hour or another 90 minutes of cold ischemic time for a lung probably doesn't negatively impact long-term survival in a meaningful way that would support this continued allocation system.

DR SETH FORCE (Atlanta, GA): That was a fantastic talk. I'm just going to be the devil's advocate here and take the con side.

I think it's a great system. I think 1 concern, or a couple concerns that you have to decide how you're going to deal with patients who are presensitized and may have a low to medium LAS score and may sit on the list for a long time, losing local donors, where they need a prospective crossmatch, to outside recipients.

The other thing to be concerned about are smaller programs that are close to dominant huge programs, and where those programs are gobbling up so many of the donors that the smaller programs around actually may cease to exist in a program like that. Then you've got a lot of recipients who, unlike kidney and liver transplant, can't travel and there actually is no longer a local program there.

So I think that I agree with you in principle that it's ridiculous that a 27-year-old CF patient died while a 70-year-old, or whatever, got lungs. But I think we do have to be careful about how a new system is created and how it's going to affect the local programs also.

DR RUSSO: I agree. You know, I think that I skipped past this slide, for whatever reason, but 1 of the things that's worth pointing out here is going back to the clinical scenario, if I can get there, is here it's not just that there is 1 or 2 patients who had higher scores, there's actually—in just this screen shot alone, there are 16 patients who had higher scores than the people who ultimately got transplanted, the number may be longer because that's where the screen shot ends. So I would say that all of those other scenarios, I mean given the number of patients that are involved in these scenarios, I'm not sure that that's a reason not to move forward.

As far as the smaller programs go, it definitely is a concern, but in the liver transplant, the IOM study looking at liver transplant, that turned out not to be true.

The other concern is for patients who are socioeconomically disadvantaged, the concern was that they would be transplanted at lower rates, and the models don't suggest that that's true. Those are things that a model doesn't necessarily prove but can be tested for.