





Extended criteria donor lungs and clinical outcome: Results of an alternative allocation algorithm

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KEYWORDS:

lung transplantation; extended criteria donors; lung allocation; allocation algorithm; primary graft dysfunction; outcomes **BACKGROUND:** Despite the scarcity of donor lungs, most potential donor organs are not offered by organ procurement organizations or are turned down by transplant centers because no suitable recipient is found according to regular allocation. Although extended criteria donors (ECDs) have recently been considered by many programs, the lung utilization rate remains < 30% in most countries. The allocation policy of Eurotransplant for donor lungs that have been turned down for donor-related medical reasons by 3 centers is to attempt a rescue offer, for which centers choose the recipients themselves. At Hannover Medical School we systematically divert these organs to more stable recipients to avoid adverse transplant outcomes. We follow up on these transplants and compare them with those following regular allocation.

METHODS: This study is an analysis of all organ offers and corresponding recipients at our center during the period from January 2010 to August 2011.

RESULTS: A total of 183 lung transplantations were performed, 111 regular donor lung offers were accepted for their intended recipient, whereas a total of 72 rescue lung offers, including all extended criteria donors, were accepted for recipients selected by our center. Donor characteristics differed between the 2 groups accordingly. Median age of ECD organ donors was significantly higher than that of regular donors (46.0 [IQR 21] vs 40.0 [IQR 22] years, p = 0.02). Donor mechanical ventilation time did not differ (3.5 \pm 4.8 vs 3.0 \pm 4.0 days, p = 0.33, not statistically significant [INS]). Donor oxygenation ratio (PaO₂:FIO₂) at time of organ offer was significantly lower (398.3 \pm 110.3 vs 423.0 \pm 97.6 mm Hg, p = 0.02). Recipients of rescue allocation organs were older than regularly selected recipients (53.7 \pm 11.7 vs 46.7 \pm 15.4 years, p = 0.0003), needed a shorter time for mechanical ventilation post-operatively (19.5 \pm 306.6 vs 68.5 \pm 718.8 hours, p = 0.02), and had shorter hospital stays (24.0 \pm 23.4 vs 47.0 \pm 43.4 days, p > 0.0001). Intensive care stay length did not differ significantly (2.0 \pm 14.5 vs 5.0 \pm 23.7 days, p = 0.21 [INS]). Post-operative survival up to 27 months after transplantation was not worse in recipients receiving rescue allocation when compared with standard allocation lung offers (81.62% vs 80.76%, p = 0.89 [INS]). The pre-operative status of the 2 recipient cohorts differed considerably, as indicated by the standard allocation group consisting of 65.8% "high-urgency" (HU)-listed patients, whereas the rescue offers were used for only 11.1% of HU-listed recipients, reflecting our center's policy.

CONCLUSIONS: Rescue allocation donor lungs can be used safely for transplantation and therefore salvaged for the donor pool. The data support our policy of accepting marginal donor lungs for stable recipients. This practice leads to very good overall survival.

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Lung transplantation is an established treatment for patients with end-stage lung disease, but the scarcity of donor organs renders timely transplant to be not possible for all patients. In 2010, a total of 1,004 patients were listed for lung transplantation in the Eurotransplant zone, but only 572 lungs were used in the same time period for transplantation. This gap between supply and demand has persisted for many years and has driven transplant centers to more liberal acceptance of marginal donor organs. 3-5

It is a well-known but unsatisfying clinical reality that only 15% to 25% of all multi-organ donors actually donate lungs. 6-8 This implies that a large number of donors not fulfilling standard criteria for lung donation. The standard criteria, as presented in Table 1,9 define an ideal donation, but many investigators have suggested that extending these criteria has not necessarily jeopardized post-operative clinical course or long-term survival of recipients. 3-5,10,11 Other publications have described a higher incidence of primary graft dysfunction within the first 72 hours after surgery using extended criteria donor organs.^{4,12} Further, a recent registry analysis of UK transplant data indicated that a positive history of smoking of the donor has a negative influence on post-operative outcome, although survival probability of lung recipients is still better with donor grafts with nicotine abuse than waiting for a suitable, non-smoking donor organ to become available.¹³ Attempts to analyze outcomes of transplantation of marginal (or extended criteria) donor lungs are, however, systematically hampered by the difficulty in defining "marginal." Lungs classified as marginal by one group may be considered a reasonably good donor organ by others.

Instead of trying to discriminate regular and marginal donor lung offers by oxygenation indices or other similarly unreliable clinical parameters, we chose to group our donated lungs into those accepted upon standard allocation by Eurotransplant and those accepted after rescue allocation. The former dictates the recipient, whereas the latter enables the transplant center to select the recipient from the local waiting list. In addition, a lung donor score according to Smits et al¹⁴ was calculated to provide a validated assessment score regarding lung quality.

On the recipient's side, lung transplant surgeons are frequently confronted with end-stage patients admitted to the intensive care unit, some already requiring mechanical ventilation or extracorporeal membrane oxygenation (ECMO), asking for an emergency lung transplant. Many transplant professionals consider allocation of a marginal donor organ justified in such "high-urgency" (HU) cases. At our center, we

Table 1 Standard Lung Donor Criteria

Age < 55 years

Clear chest X-ray

 $PaO_2 > 300 \text{ mm Hg (FIO}_2 1.0, PEEP 5 mm Hg)}$

History of smoking > 20 pack-years

Absence of chest trauma

Absence of microbiologic endobronchial organisms

Absence of malignancy

Absence of purulent secretions or signs of endobronchial aspiration

Inconspicuous virology

have, in agreement with other investigators, ^{15–17} however, made the observation in the past that outcomes are especially bad in these combinations and have developed an internal guideline essentially propagating the allocation of marginal donor organs to stable "easy" cases, such as lung emphysema recipients. Lung emphysema recipients often score low in the lung allocation score system and thus have difficulty obtaining organs. ^{18,19} Thus, they may also benefit from our internal guideline regarding marginal organs.

In this study we analyzed outcomes after lung transplantation with donor organs after standard versus rescue allocation at our center. The main objective of this analysis was to determine whether it is safe to accept marginal donor organs in rescue allocation for lung transplantation without increasing the post-operative risk for recipients, thereby potentially enhancing the evidence for further extending the donor organ pool. Using these organs for transplantation and therefore saving them concomitantly for the donor pool would not only enlarge the number of potential lung donors but also save patients with end-stage lung disease who would not have been considered for a timely transplant through regular allocation. Furthermore, the calculated lung donor score and post-operative clinical data of the respective recipient may also help in evaluating and assessing the quality of organs that have been turned down in the regular allocation process.

Methods

To assess the impact of the allocation procedure on postoperative course and survival of lung transplant patients, a retrospective analysis was performed focusing on allocation procedure and respective recipients' outcome. All lung transplantations performed at our center between January 2010 and August 2011 were divided into 2 groups, based on the allocation circumstances of the donor organ. One group included all recipients transplanted with a donor lung allocated according to standard procedures to the designated recipient. The other group included all recipients transplanted with donor lungs that were offered to our center as a rescue allocation according to Eurotransplant allocation rules. In brief, the lung allocation policy is based on urgency status, waiting time, size match and ABO blood group rules. Once a donor is reported to Eurotransplant, a recipient list with respect to the aforementioned criteria is made and the lungs are offered accordingly. If a donor lung has been turned down by at least 3 transplant centers for designated recipients due to donor-related medical reasons, or if organ loss is imminent due to an unstable donor condition, standard allocation can be switched to a rescue allocation.

The major feature of this rescue allocation is that the offers are no longer fixed to individual patients but to the transplant center, which can select any listed recipient from the local waiting list. Rescue allocation organs are offered to centers within the donor region or country that has possible recipients on the waiting list according to the previously used matching list of the regular allocation mode. If the lungs are rejected by 3 centers within this rescue allocation scheme or, in some cases, if urgent allocation is necessary due to hemodynamic instability of the donor, the lungs are offered to high-volume transplant centers in a "competitive center offer." The majority of the organs did not fulfill one or more standard lung donor criteria (Table 1) and were therefore classified as marginal organs. Also, a few organs that could not be allocated

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