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Urgent lung allocation system in the Scandiatransplant countries

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BACKGROUND: Throughout the world, the scarcity of donor organs makes optimal allocation systems necessary. In the Scandiatransplant countries, organs for lung transplantation are allocated nationally. To ensure shorter wait time for critically ill patients, the Scandiatransplant urgent lung allocation system (ScULAS) was introduced in 2009, giving supranational priority to patients considered urgent. There were no pre-defined criteria for listing a patient as urgent, but each center was granted only 3 urgent calls per year. This study aims to explore the characteristics and outcome of patients listed as urgent, assess changes associated with the implementation of ScULAS, and describe how the system was utilized by the member centers.
METHODS: All patients listed for lung transplantation at the 5 Scandiatransplant centers 5 years before and after implementation of ScULAS were included.
RESULTS: After implementation, 8.3% of all listed patients received urgent status, of whom 81% were transplanted within 4 weeks. Patients listed as urgent were younger, more commonly had suppurative lung disease, and were more often on life support compared with patients without urgent status. For patients listed as urgent, post-transplant graft survival was inferior at 30 and 90 days. Although there were no pre-defined criteria for urgent listing, the system was not utilized at its maximum.
CONCLUSIONS: ScULAS rapidly allocated organs to patients considered urgent. These patients were younger and more often had suppurative lung disease. Patients with urgent status had inferior short-term outcome, plausibly due to the higher proportion on life support before transplantation.
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Lung transplantation (LTx) may be the only option for patients with end-stage lung disease, but the number of donor organs is limited and the time until an organ becomes available is unpredictable. For patients with rapidly deteriorating condition, the waiting time may be too long to permit survival. Therefore, most organ allocation systems have rules to ensure that such patients are prioritized whenever a suitable organ becomes available.

In the United States, a lung allocation score (LAS) is calculated to prioritize patients.[1] Its implementation in 2005 was associated with a reduction in waiting list deaths, although the mechanism for this is uncertain, as an increase in the number of transplants performed occurred simultaneously. It seems likely, however, that the LAS contributed to a change in the distribution of patients receiving a LTx, favoring patients with interstitial lung disease, who are frequently older than many of the other patients listed.[2] A modified LAS was introduced in Germany in 2011 with similar effects.[3] The modified LAS is also used by Eurotransplant for international organ exchange.[4] France introduced its High-Emergency Lung Transplantation (HELTx) system in 2007, giving national priority to patients with rapid clinical deterioration, identified by certain clinical criteria. An early review of this system[5] indicated reduced post-transplant survival in such patients. However, in a later single-center study the implementation of HELTx was associated with a drastic decrease in waiting list mortality, and at that center the outcome of the high-emergency patients was not inferior.[6] In May 2017, a similar system for national organ sharing was introduced in the UK.[7] Thus, most organ allocation areas have some system for prioritizing rapidly deteriorating patients, identifying them either by clinical judgment, predefined criteria, or a scoring system, and sometimes allowing these patients access to national or supranational organ sharing to shorten their waiting time.

In the Nordic countries, there are 5 centers for LTx collaborating through the organization Scandiatransplant. Each center serves a population of approximately 5 million inhabitants and all countries have similar health-care systems, granting full and equal coverage to all citizens. In 2009, a system was introduced granting patients with urgent status supranational priority throughout the entire Scandiatransplant area,[8] hereafter termed the Scandiatransplant Urgent Lung Allocation System (ScULAS). Notably, and unlike many other organ-exchange systems, there are no pre-defined criteria for listing a patient as urgent. Instead, it is up to each center to decide who should have such urgent status. Importantly, however, each member center is limited to 3 such urgent calls per calendar year.

In this study we explore the characteristics and outcome of patients who received priority for urgency with ScULAS, assess changes in the transplant population before and after its implementation in 2009, and describe how the Scandiatransplant centers utilize the urgent call system.

Methods

Study design

All patients listed for LTx in the Scandiatransplant area (i.e., Denmark [Copenhagen], Finland [Helsinki], Norway [Oslo], and Sweden [Gothenburg and Lund]) in the period 2005 to 2014 were included in the study. To evaluate the changes associated with implementation of ScULAS, patients were divided into 2 groups: a pre-implementation period (January 1, 2005 to April 30, 2009 [1,580 days]) and a post-implementation period (May 1, 2009 to December 31, 2014 [2,070 days]). Patient and waiting list data were retrieved from the Scandiatransplant registry. Patients were categorized into 6 diagnosis groups, including: (1) obstructive; (2) restrictive, (3) suppurative (e.g., cystic fibrosis [CF] and non-CF bronchiectasis); (4) vascular; (5) transplant graft failure; and (6) other.

Organization of ScULAS

Before the ScULAS was introduced, each center allocated available organs to compatible patients on the waiting list within each country, prioritizing according to clinical judgment. There was no system for international organ exchange to patients with high urgency. ScULAS went into effect on May 1, 2009,[8] after which all patients listed for LTx were categorized as either urgent or regular according to clinical judgment. Among those given urgent status, patients on life support (extracorporeal membrane oxygenation [ECMO] or mechanical ventilation [MV]) were considered as Priority 0, whereas Priority 1 included patients who were not on life support, but had rapid progression of organ failure and poor short-term prognosis as defined by the responsible center. In this report, Priority 0 and Priority 1 will hereafter be termed in aggregate as urgent. Furthermore, patients initially listed as regular and then changed to urgent are presented as urgent in the Results. Patients not given urgent status were considered as Priority 2 (hereafter called regular). Each center had the right to claim supranational priority for 2 urgent patients per year, which increased to 3 in March 2010. To list a patient as urgent, notice was given by the team of responsible physicians to the transplant coordinator on call, who submitted the request and all necessary recipient information electronically in the Scandiatransplant system. Notification of the new listing was then automatically given to transplant coordinators at all centers. If necessary, recipient serum was sent to potential donor centers. All compatible donor lungs were first mandatorily offered to Priority 0 patients and then Priority 1 patients in the entire Scandiatransplant area. If multiple recipients were listed with the same priority, the organ was allocated to the center with the highest rank on a rotating list. Local and then national urgent recipients were prioritized before urgent recipients in other Scandiatransplant countries. If no suitable urgent patient existed in the Scandiatransplant area, the organ was offered to regular patients locally or nationally, and then to regular patients in other Scandiatransplant countries according to the rotating list.

Statistical analysis

Continuous data with non-normal distributions are presented as median and interquartile range (IQR) and compared using the non-parametric Mann–Whitney *U*-test. Categorical variables are presented as count and percent and compared using Fisher's exact test. $p < 0.05$ was considered statistically significant. Recipient survival was assessed using Fisher's exact test and log-rank test. Log-rank power calculations were performed using the Freedman method. STATA version 15 for Macintosh (StataCorp LP, College Station, TX) was used for all statistical analyses. Prism version 6 for Macintosh (GraphPad Software, Inc., La Jolla, CA) was used to create graphs and illustrations.

Ethical considerations

The study used anonymized data from the Scandiatransplant registry authorized by the regional ethics committees for the respective transplant centers.

Results

Characteristics of patients listed as urgent

For the post-implementation period, the characteristics of patients listed as urgent compared with patients listed as regular are summarized in Table 1. Notably, patients listed as urgent were younger (Figure 1), but there were no significant differences in gender, height, predicted total lung capacity (pTLC), or blood type. Furthermore, patients in the urgent cohort were less likely to have a negative panel-reactive antibody (PRA) test. There were very few patients with obstructive lung disease, and there was a higher proportion of patients with suppurative and other diagnoses on the urgent list compared with the regular list. Also, there was a trend toward a higher proportion of patients with restrictive disease in the urgent group. Patients listed as urgent were more commonly on ECMO or MV compared with patients listed as regular.

There was no significant difference in donor age between urgent and regular recipients (51 vs 49 years, $p = 0.364$), but there was a trend toward a lower proportion with a positive donor smoking history in the urgent group (18% vs 35%, $p = 0.055$). EVLP was used for only 3% of the lungs given to urgent recipients. Of the urgent calls that resulted in transplantation, 63% of organs were from a donor center located in a different Scandiatransplant country than the transplant center.

Time and mortality on waiting list

A higher proportion of patients with urgent status died or were permanently withdrawn during the first year after listing compared with regular patients (9.9% vs 3.6%, $p = 0.020$; Figure 2). There was a trend toward a higher proportion of patients with positive PRA among patients who died or were permanently withdrawn compared with patients who were transplanted on the urgent list (57% vs 21%, $p = 0.063$), but not those on the regular list (18% vs 16%, $p = 0.607$). Of the 7 patients who were not transplanted after urgent listing, 5 died while waiting for LTx and 1 recovered and was withdrawn from the waiting list. The patients who died on the urgent list were all women, 5 were on life support, 4 were listed for retransplantation, and 4 had blood type O (Table 2).

Not surprisingly, a higher proportion of the patients listed as urgent were transplanted during the first year after listing compared with those listed as regular (90% vs 27%, $p < 0.001$; Figure 2). Although 81% of those listed as urgent were transplanted within 4 weeks, 86% within 8 weeks, and 89% within 12 weeks, the corresponding proportions for those with regular status were 4.3%, 5.9%, and 7.6%, respectively (Figure 2).

In the post-implementation period, 81 patients were on life support intended as bridge to transplantation. Of these, 6 (7.4%) recovered before they were transplanted and were delisted after a time on waiting list ranging from 6 days to 336 days, whereas 15 (19%) died before transplant. Of the 15 who died, only 5 had received urgent status whereas 10 had not (time on waiting list 3 to 39 days and 1 to 352 days, respectively, $p = 0.951$). For the 10 patients on life support who died on the waiting list and did not have urgent status, urgent call was unavailable in only 1 case. Among the 59 patients who were transplanted from life support, 33 (56%) had urgent status and 26 (44%) had not (time on waiting list 0 to 23 days and 0 to 445 days, respectively, $p = 0.291$). Notably, having urgent status significantly increased the chance of being transplanted for patients on life support ($p = 0.026$); however, there was no significant difference in waiting list mortality for patients on life support with or without urgent status (13% vs 24%, $p = 0.258$).

Post-transplant graft survival

When comparing patients listed as urgent with patients listed as regular, 30-day graft survival (90.6% vs 96.3%, $p = 0.042$) and 90-day graft survival (87.5% vs 94.5%, $p = 0.048$) were significantly inferior among patients listed as urgent, but there were no differences in 1-year graft survival (81.3% vs 85.5%, $p = 0.361$) or overall graft survival ($p = 0.705$). However, this must be interpreted carefully as our analysis was unable to detect a hazard rate <1.6 with 80% power due to the low number of patients in the urgent group. When analyzing patients without life support exclusively, we found no differences in 30-day graft survival (96.8% vs 97.1%, $p = 0.612$), 90-day graft survival (93.6% vs 95.5%, $p = 0.649$), 1-year graft survival (93.6% vs 86.2%, $p = 0.415$), or overall graft survival ($p = 0.212$). Moreover, for all patients listed after introduction of ScULAS, we found significantly lower graft survival in those on life support compared with those not treated with life support ($p = 0.020$). There was no difference in graft survival in the patients on life support when comparing those with and those without urgency status ($p = 0.377$).

Utilization of ScULAS

The timing of urgent calls at the 5 centers is shown in Figure 3. Throughout the entire post-implementation period, the proportion of patients who died on the waiting

Table 1 Characteristics of Patients on Waiting List for Lung Transplantation From May 1, 2009 to 2014, Stratified by Urgent Status

	Waiting list status		
	Regular	Urgent	p
Number	952	71	
Age at listing (years)	54 (45 to 59)	40 (29 to 50)	<0.001[a]
0 to 16 years	19 (2.0%)	5 (7.0%)	0.021[a]
17 to 39 years	141 (15%)	29 (41%)	<0.001[a]
40 to 60 years	568 (60%)	33 (46%)	0.034[a]
>60 years	224 (24%)	4 (5.6%)	<0.001[a]
Males	460 (48%)	30 (42%)	0.389
Height (cm)	170 (163 to 177)	168 (163 to 179)	0.520
pTLC (liters)	5.7 (5.0 to 7.1)	5.4 (5.0 to 7.0)	0.348
Blood type (ABO)			0.547
O	370 (39%)	33 (46%)	
A	437 (46%)	28 (39%)	
B	97 (10%)	8 (11%)	
AB	48 (5.0%)	2 (2.8%)	
Diagnosis			
Obstructive	400 (42%)	2 (2.8%)	<0.001[a]
Age at listing (years)	56 (52 to 60)	45 (43 to 48)	0.042[a]
Restrictive	270 (28%)	28 (39%)	0.057
Age at listing (years)	56 (49 to 61)	49 (39 to 52)	<0.001[a]
Suppurative	127 (13%)	21 (30%)	0.001[a]
Age at listing (years)	35 (24 to 45)	27 (20 to 41)	0.065
Vascular	56 (5.9%)	6 (8.5%)	0.433
Age at listing (years)	39 (22 to 51)	39 (34 to 50)	0.668
Tx graft failure	59 (6.2%)	7 (9.9%)	0.212
Age at listing (years)	49 (39 to 57)	36 (29 to 46)	0.047[a]
Other	40 (4.2%)	7 (9.9%)	0.038[a]
Age at listing (years)	42 (30 to 54)	34 (22 to 46)	0.256
Tx procedure (planned)			
BLTx	782 (82%)	68 (96%)	0.002[a]
SLTx	157 (16%)	2 (2.8%)	0.001[a]
HLTx	13 (1.4%)	1 (1.4%)	0.999
Life support			
ECMO	22 (2.3%)	32 (45%)	<0.001[a]
MV	20 (2.1%)	7 (9.9%)	0.002[a]
Last follow-up			
6MWT (meters)	295 (205 to 397)	296 (148 to 487)	0.775
FEV_1 (% of predicted)	28 (20 to 45)	36 (29 to 50)	0.011[a]
HLA immunization (PRA)			
No immunization (PRA 0%)	774 (81%)	47 (66%)	0.005[a]
Low immunization (PRA 1% to 9%)	29 (3.1%)	3 (4.2%)	0.482
Medium immunization (PRA 10% to 79%)	98 (10%)	9 (13%)	0.545
High immunization (PRA 80% to 100%)	23 (2.4%)	4 (5.6%)	0.111
Not analyzed	28 (2.9%)	8 (11.3%)	0.002[a]

Continuous data are presented as median (interquartile range). Categorical data are presented as count (%). 6MWT, 6-minute walk test; BLTx, bilateral lung transplantation; ECMO, extracorporeal membrane oxygenation; FEV_1, forced expiratory volume in 1 second; HLTx, heart and lung transplantation; MV, mechanical ventilation; PRA, panel-reactive antibody; pTLC, predicted total lung capacity; SLTx, single lung transplantation; Tx, transplant.

[a]$p < 0.05$.

list varied from 6.4% to 18% between centers, and the utilization of available urgent calls varied from 71% to 94%. In some years, however, 1 or more centers used all available urgent calls. Thus, on average, the centers were out of urgent calls 0.7 to 4.1 months per year (all-center average: 2.1 months) during the study period (Figure 3). There was no increased occurrence of death on the waiting list at the end of calendar years when all centers and post-implementation years were studied in aggregate.

Changes related to implementation of ScULAS

When comparing the pre- and post-implementation periods, we found an increase in the average number of transplants from 113/year to 136/year (+20%), while the average number of new patients listed increased from 141/year to 161/year (+14%). The donor utilization rate changed from 29.5% to 31.7% (+7%). Consequently, a significantly higher proportion of listed patients were transplanted and a

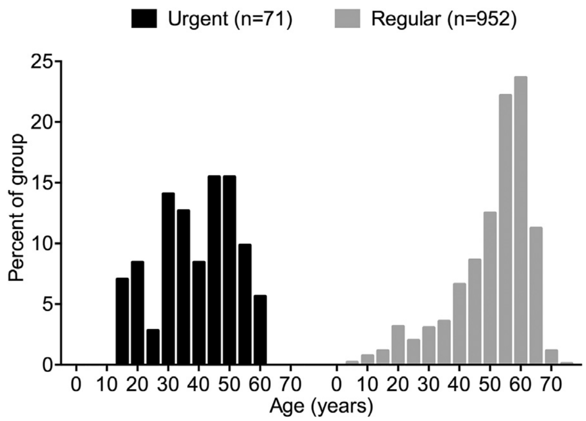

Figure 1 Age distributions for patients on the waiting list for lung transplantation listed as urgent or as regular from May 1, 2009 to 2014.

significantly lower proportion died or were withdrawn from the waiting list (Table 3). Moreover, in the latter period, the waiting list included a higher proportion of patients with restrictive diseases (22% vs 29%, $p < 0.001$) and a lower proportion of those with obstructive diseases (48% vs 39%, $p < 0.001$) and "other" diseases (7.2% vs 4.6%). Similar changes were observed among those who were transplanted (Table 3), with a reduction in the proportion of LTx recipients with obstructive lung disease and an increase in LTx recipients with restrictive lung disease in the post-implementation period. Furthermore, there was an increase in the proportion of patients who were bridged to transplantation using life support.

Discussion

The key findings in this study are: (1) ScULAS rapidly allocates organs to patients listed as urgent; (2) ScULAS gives priority to younger patients and to patients with suppurative and possibly also to those with restrictive lung diseases; (3) although the short-term graft survival is inferior in patients on life support given urgent status, we found no difference in graft survival in urgent patients who were not on life support; and (4) access to supranational priority was not utilized to its maximum at all centers.

As expected, waiting time was considerably lower for patients on the urgent list compared with the regular list, but approximately 10% of patients nevertheless waited >4 weeks after urgent listing. In contrast to the HELTx system in France, where the maximally permitted time on the HELTx list is 2 weeks (exceptions are allowed in special cases), there is no limit to how long a patient can be listed as urgent in ScULAS. This may give individual centers an incentive to list as urgent not necessarily those with short expected survival, but also those who may be expected to have a particularly long waiting time on the national regular list, such as patients with combinations of blood type and height that are uncommon in the donor pool. Importantly, we saw no overrepresentation of such patients among the urgently listed. We did find that the proportion of those with negative PRA was slightly lower in the urgent group, but our data do not support any plausible explanation for this observation. Furthermore, only about half of the urgent patients were transplanted after 2 weeks, indicating that a time limit similar to that in the HELTx may not be suitable in this system.

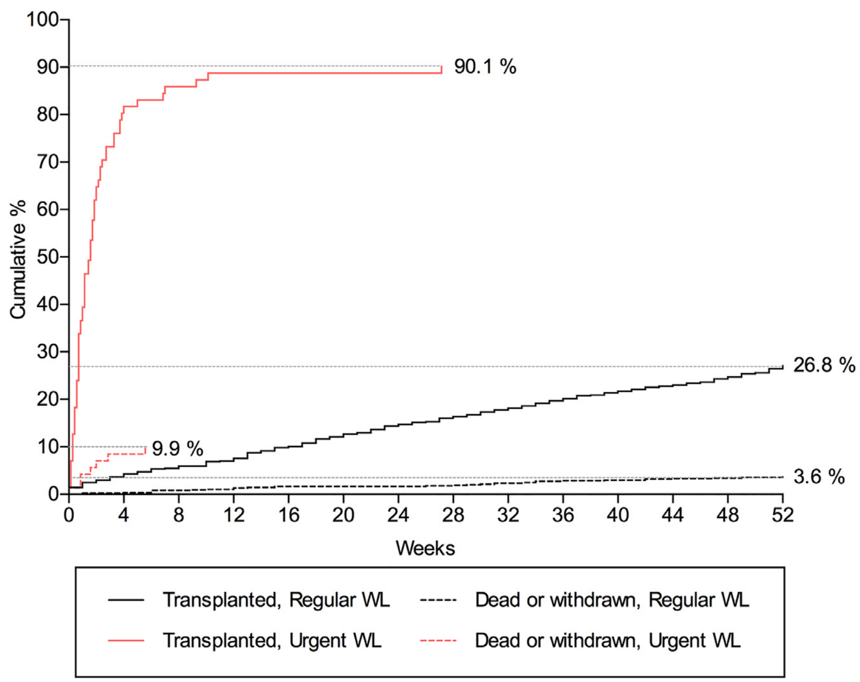

Figure 2 Cumulative proportions of patients on the waiting list for lung transplantation who were transplanted or died or were withdrawn from the waiting list during the first year after listing.

Table 2 Characteristics of Patients With Urgent Status on Waiting List Who Died While Waiting

No.	Life support	Age at listing (years)	Sex	Height (cm)	ABO	Lung pathology	ReTx	HLA immunization (PRA)	Time on regular waiting list before given urgent status (days)	Time on urgent waiting list (days)
1	ECMO	29	F	165	0	Suppurative	Yes	10% to 79%	13	39
2	ECMO	38	F	169	0	Vascular	No	10% to 79%	2	11
3	ECMO	39	F	175	0	Vascular	Yes	0%	0	14
4	MV	43	F	166	A	Suppurative	No	0%	0	3
5	ECMO	55	F	160	0	Restrictive	Yes	0%	0	6
6	None	28	F	163	A	Suppurative	Yes	80% to 100%	94	6

ECMO, extracorporeal membrane oxygenation; MV mechanical ventilation; ReTx, retransplantation.

The proportion of patients given priority due to urgency in the ScULAS seems lower than the proportion that may be considered to have comparably high urgency elsewhere. In the USA and Germany, the proportion of patients transplanted with a LAS of >50 were 29%[2] (2011) and 33.5%[4] (2011 to 2012), respectively. At 7 LTx centers in France, 14.2% (2007 to 2011) of the transplanted patients were on the high-emergency waiting list.[4] Notably, although the fixed numbers defined by the Scandiatransplant system would limit the urgent proportion to only 8.3% of the listed volume, the actual utilization rate was even lower (6.9%), indicating that the system was not being overused, and that the transplant centers honor the intent of the system despite the absence of pre-defined criteria.

Similarly to the HELTx system,[6] our findings show that the patients listed as urgent are younger than those listed as regular. Moreover, similar to the French HELTx system, a higher proportion of patients with suppurative lung diseases and almost no obstructive patients are listed as urgent compared with the regular waiting list. Thus, despite the absence of criteria, the patients listed as urgent in the ScULAS appear to resemble those given such status in other allocation systems. However, almost half of the patients bridged with life support were not given urgent status and ensuing supranational priority. Thus, although urgent status is granted by default to those bridged with life support in many other allocation systems, and, although being on life support does lead to a significantly higher LAS where such a system is used, it seems that in the clinical judgment of the individual centers in Scandiatransplant not all such patients merit urgent allocation. Yet, the fact that 10 of 15 patients with life support 10 died while waiting and did not have urgent status, even though it was available in all cases but 1, could be an argument for automatically granting urgent status to patients on life support.[10] Furthermore, in contrast to the allocation systems in the UK and France, where retransplantations in general are not granted urgent status, 9.9% of urgent patients in ScULAS were listed for retransplantation.

There was inferior short-term survival in recipients given urgent status, and, although there was no significant difference in overall survival, our statistical power to detect such a difference was limited. It is likely that the inferior short-term survival in the urgent group was due to the higher proportion with life support in this group, as there was no difference when patients without life support were analyzed separately. This is in line with other studies that have shown that the use of life support is associated with inferior survival.[9] As in other allocation systems, patients bridged to transplant using life support seem to be given priority in the ScULAS, and urgent listing did offer a higher likelihood of transplantation in these patients. Thus, the ScULAS seems to prioritize the principle of equity over the principle of utility.

Several changes occurred simultaneously with the implementation of ScULAS. First, the number of transplantations increased, which may be the main reason for the decrease in waiting list mortality. Second, there was a shift toward listing more patients with restrictive and fewer patients with obstructive diseases. In addition, the number of patients on life support increased. Although it is not likely that the ScULAS influenced the preference for restrictive over obstructive patients, the implementation of ScULAS may have encouraged listing of patients who were previously considered too ill to be listed for transplantation, as the waiting time would be too long. In particular, it may have reduced the barrier for using life support as a bridge to transplantation.

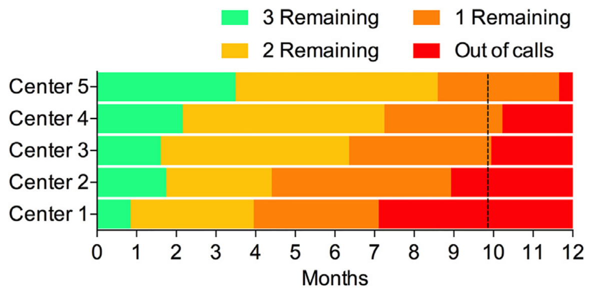

Figure 3 Average utilization of the Scandiatransplant Urgent Lung Allocation System from May 1, 2009 to 2014. Bars indicate average percent for the year with 3, 2, 1, or 0 urgent call(s) remaining for each center.

Limitations

This study has several limitations. First, was is a retrospective, registry-based study. Second, as in the United States and in Eurotransplant, the introduction of the urgency system occurred in the middle of a general increase in the number of LTxs performed. This may preclude conclusions about the effects of the allocation system on the overall

Table 3 Characteristics of Patients Before and After Implementation of Scandiatransplant Urgent Lung Allocation System

	Pre-implementation (January 1, 2005 to April 30, 2009)	Post-implementation (May 1, 2009 to December 31, 2014)	*p*
Patients on WL	733	1,023	
Died or withdrawn from WL	133 (18%)	143 (14%)	0.041[a]
On WL at the end of period	112 (15%)	108 (11%)	0.003[a]
Transplanted patients	488 (67%)	772 (75%)	<0.001[a]
Age (years)	54 (41 to 58)	53 (43 to 59)	0.605
Males	251 (51%)	399 (52%)	0.954
Height (cm)	170 (164 to 177)	171 (165 to 178)	0.403
Blood type (ABO)			0.367
O	184 (38%)	270 (35%)	
A	238 (49%)	377 (49%)	
B	47 (9.6%)	79 (10%)	
AB	19 (3.9%)	46 (6.0%)	
Diagnosis			
Obstructive	235 (48%)	295 (38%)	0.001[a]
Restrictive	114 (23%)	228 (30%)	0.016[a]
Suppurative	67 (14%)	126 (16%)	0.229
Vascular	28 (5.7%)	46 (6.0%)	0.903
ReTx	20 (4.1%)	46 (6.0%)	0.156
Other	24 (4.9%)	31 (4.0%)	0.480
Life support			
ECMO	14 (2.9%)	42 (5.4%)	0.035[a]
MV	5 (1.0%)	17 (2.2%)	0.184

Continuous data are presented as median (interquartile range). Categorical data are presented as count (%). ECMO, extracorporeal membrane oxygenation; MV, mechanical ventilation; ReTx, retransplant; WL, waiting list.
[a] $p < 0.05$.

performance of the LTx activity, particularly concerning waiting list survival. Third, certain clinical data (e.g., forced expiratory volume in 1 second and 6-minute walk distance) may have been less available in the urgent cases, leading to an ascertainment bias.

In conclusion, we found that the ScULAS rapidly allocates organs to patients considered urgent by granting supranational priority to a limited number of patients. Younger patients and patients with suppurative lung diseases were more often given urgency status, whereas patients with obstructive disease were rarely given such status. Furthermore, post-transplant graft survival among those listed as urgent was lower in the short term, which seemed to be related to the higher proportion of patients bridged with life support in the urgent group. Although the ScULAS was limited to a fixed number per year per center and had no pre-defined criteria for urgent listing, the system was not utilized to its maximum.

Disclosure statement

The authors have no conflicts of interest to disclose. Some of the authors have been involved in the planning and design of the Scandiatransplant Urgent Allocation System. A.M.H. is chair of the Scandiatransplant Heart and Lung Group, which is a collaborative group under Scandiatransplant. This work was supported by a research grant from Scandiatransplant and from the Norwegian Respiratory Society. The authors thank Ilse Duus Weinreich, Scandiatransplant Aarhus, Denmark, and Petra Westlund, Sahlgrenska University Hospital, Gothenburg, Sweden, for their valuable contributions to this study.

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