(73)

Increasing Lung Transplant Availability with Normothermic Ex Vivo Lung Perfusion (EVLP) at a Dedicated Facility and a Centralized Lung Evaluation System (CLES): 3-Year Outcomes

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Purpose: This study is the first prospective, multicenter trial to examine the safety and feasibility of a dedicated EVLP facility to evaluate lungs declined for standard transplantation in the US. As a follow-up to one year safety endpoints in the trial, three-year data (February 11, 2022) for UNOS-reported bronchiolitis obliterans syndrome (BOS) and 3-year survival status were used as measures of the longer-term relative safety of the centralized lung evaluation system (CLES) model compared to lungs accepted for standard transplant.

Methods: Seven transplant centers from the Midwest and Eastern US referred 105 lungs that had been rejected by standard transplant criteria to a dedicated EVLP facility using a CLES (NCT02234128). Lungs were perfused and ventilated using the Toronto EVLP protocol. Following CLES, 63 were accepted for transplantation (utilization rate of 60%). The matched control group consisted of 49 lungs transplanted without the use of EVLP. Bronchiolitis obliterans syndrome (BOS) was defined per protocol as airflow limitation in the absence of other etiologies and did not require histopathology documenting BOS. BOS diagnosis was graded in accordance with 2014 ISHLT guidelines as follows: forced expiratory volume in 1 second (FEV_1) 66-80% of baseline was grade 1, FEV_1 51-65% of baseline was grade 2, and FEV_1 <50% of baseline was grade 3. Three-year follow-up data was obtained through UNOS based on OPTN data as of February 11, 2022.

Results: Three years post-transplant, BOS was reported in 7 (10.61%) CLES lung recipients and 7 (14.29%) standard transplant recipients (controls) (Table 1). Recipients without BOS were reported in similar proportions at 22.73% (n=15) and 22.45% (n =11) for CLES and control recipients, respectively. A high proportion of recipients in both groups had an unreported or unknown BOS status, therefore statistical tests were not performed for this measure. At three years post-transplant, survival was 75.8% (n = 50) for CLES lung recipients and 73.5% (n = 36) for standard transplant controls. Survival rates over three years were not significantly different between CLES and control lung recipients (p =0.8067).

Conclusions: These findings suggest similar longer-term outcomes for recipients of standard lung and CLES lung transplants.

Table 1. UNOS reported Bronchiolitis Obliterans Syndrome (BOS) at 3 years post-transplant

n (%)	CLES n=66	Control n=49
No BOS	**15 (22.73)**	**11 (22.45)**
Not Reported/Unknown	44 (66.67)	31 (63.27)
Total Yes	**7 (10.61)**	**7 (14.29)**
Grade 1	0 (0)	2 (4.08)
Grade 2	1 (1.52)	1 (2.04)
Grade 3	2 (3.03)	1 (2.04)
Grade OP	1 (1.52)	1 (2.04)
Grade UNK	3 (4.55)	2 (4.08)

Based on OPTN data as of February 11, 2022. This work was supported in part by Health Resources and Services Administration contract 234-2005-370011C. The content is the responsibility of the authors alone and does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government. BOS: Bronchiolitis Obliterans Syndrome; CLES: Centralized Lung Evaluation System; OPTN: Organ Procurement and Transplantation Network; UNOS: United Network for Organ Sharing

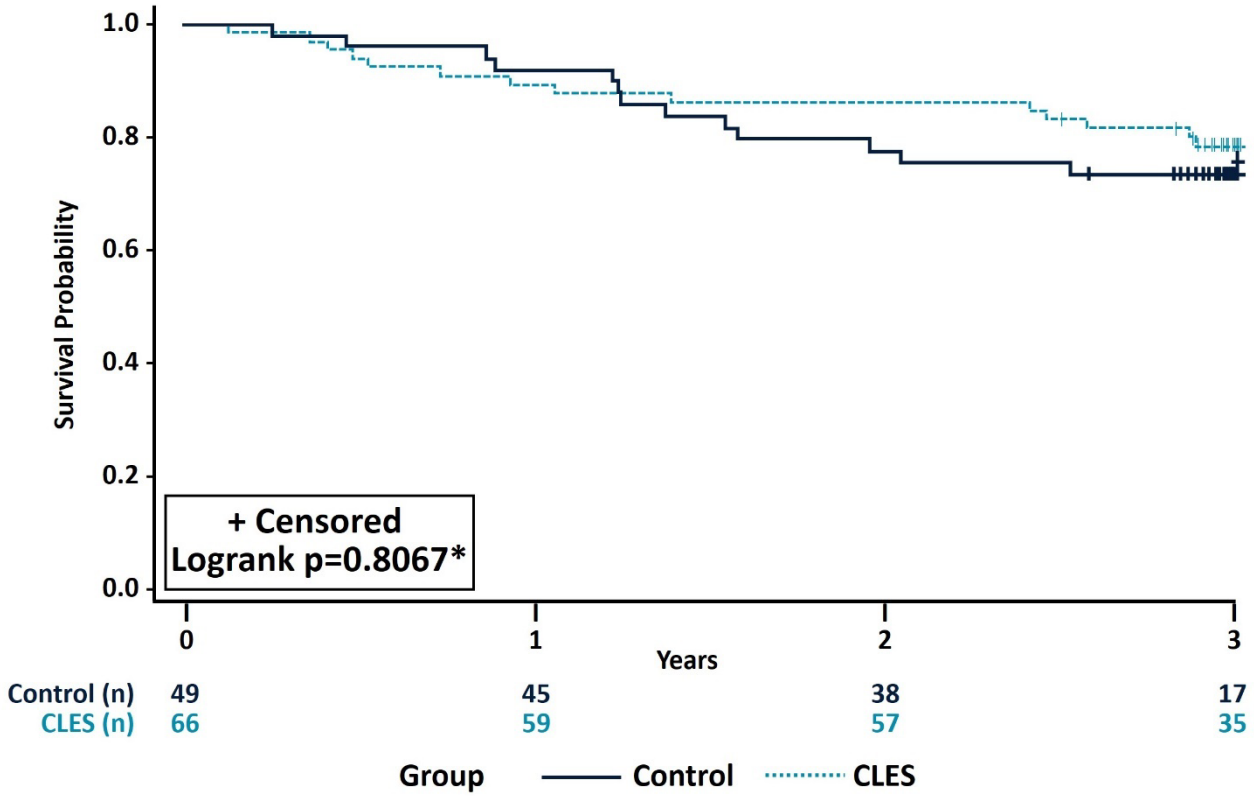

Figure 1. Recipients of EVLP lungs evaluated using a centralized lung evaluation system (CLES) had similar survival rates out to 3 years compared recipients of lungs accepted for standard transplant (control). *p-value is from log-rank test stratified by single or double lung transplant and lung allocation score Disease Diagnosis Group (LAS-DDG).