

Ex Vivo Perfusion with lung donation after circulatory death: an analysis of transplantable outcome with the time interval from withdrawal of life-sustaining treatments to start of cold flush perfusion

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INTRODUCTION

- In 2016, only 16.9% of U.S. lung donations involved donation after circulatory death (DCD).
- Improved DCD lung utilization has the potential to increase lungs for transplant and thus reduce waitlist mortality.
- DCD lungs face hemodynamic instability and warm ischemia after withdrawal of life-sustaining treatments (WLST) until initiation of cold flush (CF) perfusion.
- Currently, there is no method of evaluating static cold stored lungs and for transplant.
- Ex vivo lung perfusion (EVLP) is a technique which may permit extended preservation and assessment of donor lungs outside of the body.

PURPOSE

- The aim of this study is to compare WLST to in situ CF time with transplant suitability determination of a continuous series of 10 DCD lung EVLP cases.

METHODS

- Following procurement of DCD lungs and EVLP, WLST to CF time and recipient Lung Allocation Scores (LAS) were collected.
- EVLP was using the Toronto method and it was a stand-alone facility with multiple trial sites.
- While undergoing normothermic EVLP, lungs were assessed by the transplant center through hourly physiologic and metabolic data, trends, real-time radiographic imaging and bronchoscopy.
- Using these parameters, a suitability determination was made for the organ by transplant center staff.
- The WLST to CF times were categorized into 3 EVLP groups: less than 30 minutes, 30 to 60 minutes and greater than 60 minutes to compare to suitability decision outcome (transplant vs non-transplant).
- T-test and Chi Square analyses were performed to determine statistical difference or similarity among the 3 EVLP groups.

RESULTS

- 10 DCD lungs were included in this study with a mean WLST to CF time of 44.8 min (range: 19-88 min.).
- Following EVLP, 6 DCD lungs were deemed suitable for transplant (60%).
- There was no T-test statistical difference in mean WLST to CF times between the non-transplant group (32.5± 13.0 min.) and transplant group (53±27.4 min.)(Fig.1).

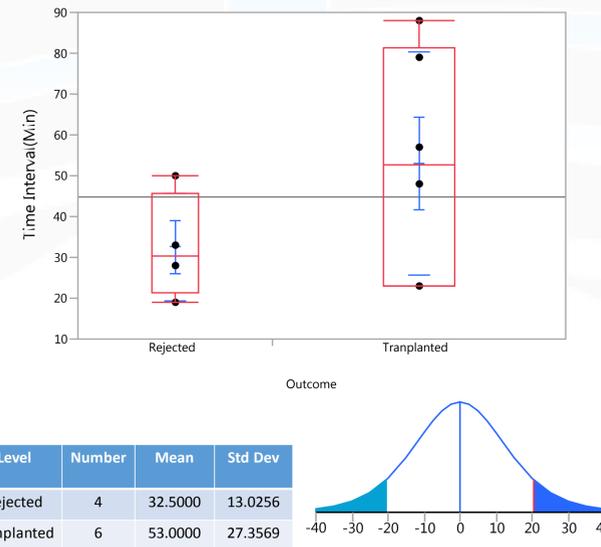


Fig.1 T-test statistics showed no difference in mean WLST to CF times between the non-transplant group and transplant group.

RESULTS (cont'd)

- In the transplant group, the maximum WLST to CF time was 88 min. in contrast to the non-transplant group time of 50 min.
- There was no Chi-Square statistical difference in suitability determination among the less than 30 min., 30 to 60 min. and greater than 60 min. groups(Fig.2).
- The LAS scores ranged from 32.7 to 43.9 for the five transplants taking place within the U.S.

Count	Rejected	Tranplanted	Total
Total %			
1-30min	2 20.00	2 20.00	4 40.00
31-60min	2 20.00	2 20.00	4 40.00
61-90min	0 0.00	2 20.00	2 20.00
Total	4 40.00	6 60.00	10

N	DF	-LogLike	RSquare (U)
10	2	1.1849392	0.1761
Test		ChiSquare	Prob>ChiSq
Likelihood Ratio		2.370	0.3058
Pearson		1.667	0.4346

Fig.2 Time groups by Outcome and Contingency Analysis showed no difference in suitability determination among the less than 30 min., 30 to 60 min. and greater than 60 min. groups.

CONCLUSION

- With a limited number of DCD cases in this single facility study, EVLP involving extended preservation and assessment of DCD lungs suggests a viable path forward to continue to study EVLP for potential transplant benefit following deceased donor WLST.
- Further, WLST to CF time intervals leading to transplant yielded no statistical difference between shorter and longer WLST to CF intervals.

REFERENCES

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DISCLOSURE

- The EVLP system used to assess the lungs for this report is currently undergoing a clinical investigation in the United States CLINICAL TRIAL PXUS 14-001
- The system is for Investigational Use Only.
- Data presented do not reflect the full dataset anticipated under the clinical protocol design
- Conclusions drawn from these data are preliminary.