

# 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.

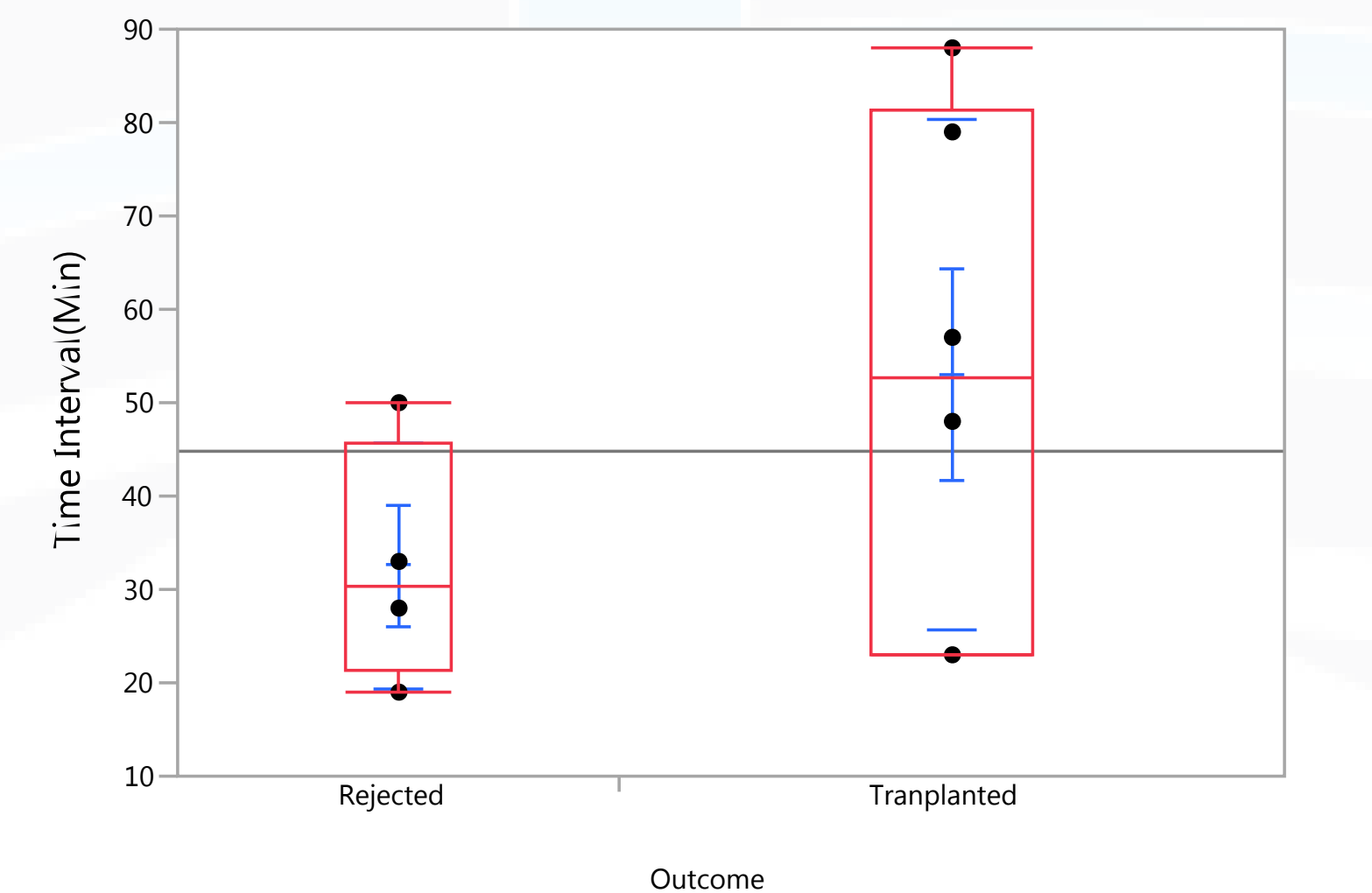
## METHODS

- 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).



| Level        | Number | Mean    | Std Dev |
|--------------|--------|---------|---------|
| Rejected     | 4      | 32.5000 | 13.0256 |
| Transplanted | 6      | 53.0000 | 27.3569 |

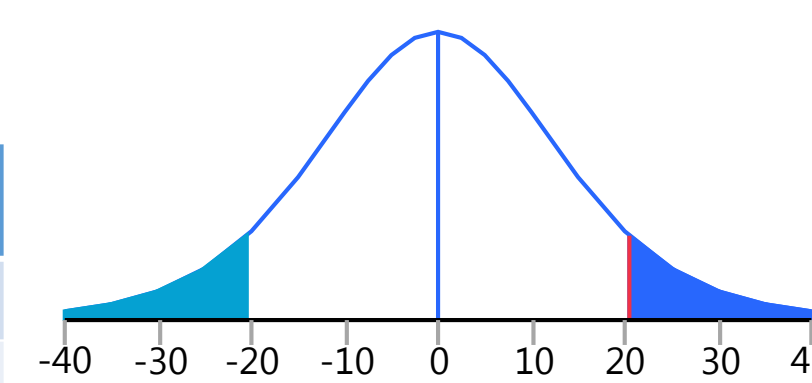


Fig.1 T-test statistics showed no difference in mean WLST to CF times between the non-transplant group and transplant group.

## 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<br>20.00 | 2<br>20.00  | 4<br>40.00 |
| 31-60min | 2<br>20.00 | 2<br>20.00  | 4<br>40.00 |
| 61-90min | 0<br>0.00  | 2<br>20.00  | 2<br>20.00 |
| Total    | 4<br>40.00 | 6<br>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

- M Cypel, Keshavjee S, et.al, New England Journal of Medicine 364 (15), 1431-1440
- ClinicalTrials.gov identifier: NCT02234128
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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.