

OxyRVAD for total right heart and respiratory support

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Introduction: We are developing Compact Paracorporeal OxyRVAD for Total Right Heart and Respiratory Support for end stage chronic lung diseases with combined right heart and respiratory failure.

1. Development of New OxyRVAD system- 5 days study:

Our new OxyRVAD consists of an egg-size centrifugal pump with heparin saline purged needle roller bearings system and an ultra-low resistant artificial lung (AL) with 2.0 m² surface area of polypropylene fiber based on our BioLung Tech. Main pulmonary artery and right heart were exposed through a left 5th intercostal thoracotomy in five anesthetized sheep (33-42 Kg). General anesthesia was introduced by Ketamin follow by Halothane inhalation through Tracheo intubation. Femoral artery cannulation and PA Swan-Ganz catheter placed for hemodynamic monitoring. Sugery was perform through left 4th intercostal thoracotomy and pericardium was open to expose main PA and right atrium. The outlet cannula graft anastomosed to main pulmonary artery and drainage cannula to right atrial appendage . The pump and artificial lung were attached paracorporeally for a RA-PA configuration(Figure1). The blood from the right atrium was pumped through the artificial lung in which it was oxygenized then into the pulmonary circulation. Thoractomy were closed with cannula pass through and Sheep transfer to ICU and allow to total recovery. Hemodynamics and gas exchange were directly monitored. Heparin infusion was titrated to ACT 250-300. Results: All five sheep survived the surgery. Two sheep expired because of pump electromechanical accident during transportation. Other three successfully recovered from anesthesia and experienced stable hemodynamics and showed total right heart support (pumping flow: 3.4-5.8L/min, CVP:-2-6 mmHg and PAP: 32-43 mmHg) and total lung support (post AL PaO₂: 342- 567 mmHg and PCO₂: 23-34 mmHg, PaO₂:167—368 mmHg and PaCO₂:29-35 mmHg).Conclusion: The compact paracorporeal OxyRVAD supplies alert sheep with total assistance of the right heart and lungs.

2. OxyRVAD with MicroMed Axial flow pump and Affinity artificial lung- 14 days Study.

Above new prototype of pump and artificial lung are not designed for long term study. We use commercial available artificial lung(affinity) and well fabricated clinical axial flow pump (MicroMed) to seek more than two week right and respiratory support.

The OxyLVADsystem (Figure 1) is composed of a MicroMed axial flow pump (MicroMed, Houston) and either an Affinity® AL (Medtronic, Minneapolis) 2.5 m² surface area of Trillium coated polypropylene fiber **Drainage cannula (Thoratec® atrial cannula) and Outlet Infusion cannula (12 mm diameter anti-kinking crimped vascular graft glue to 3/8" Tygon tubing).**

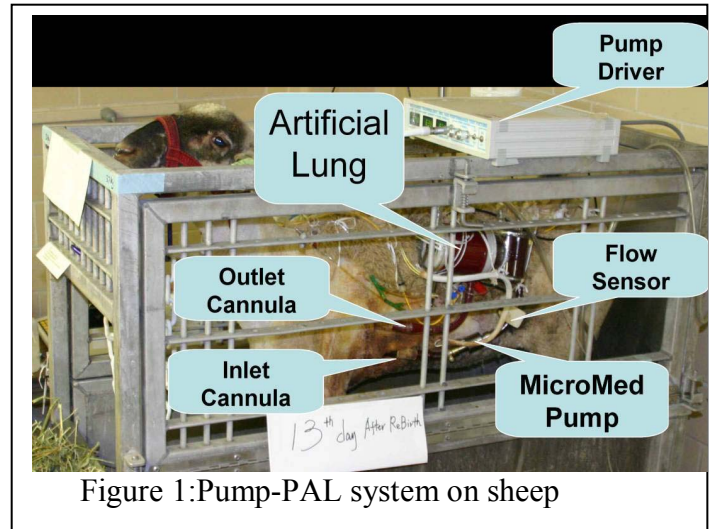


Figure 1: Pump-PAL system on sheep

There is 8 sheep (32-46 Kg) involved in this study. The Anesthesia, Surgical attachment, recovery, and monitoring is the save as above.

Result: All 6 sheep survive the surgery transfer to ICU and recovered from anesthesia. There are one sheep experiences severe bleeding and sacrificed at 6th hours. Another one experience very low pumping flow

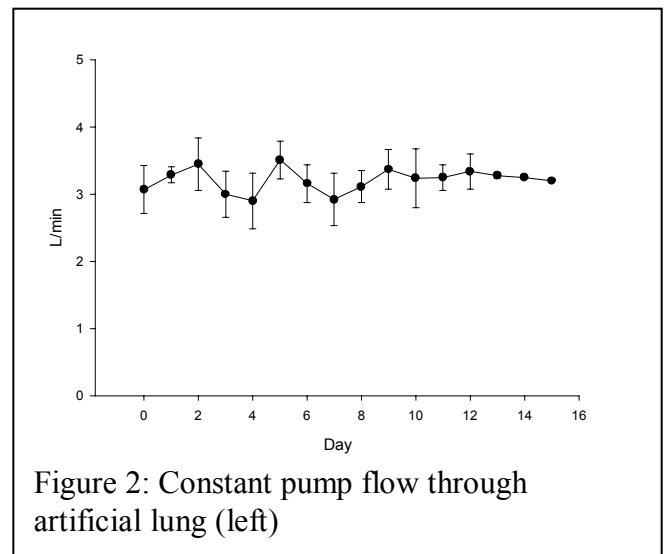
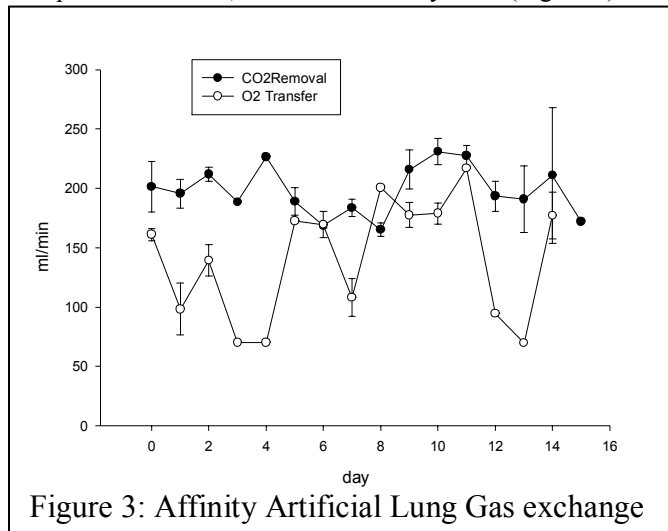


Figure 2: Constant pump flow through artificial lung (left)

sacrifice at 5th hours, autopsy study shown the inlet of atrial cannula occluded from inlet thrombosis. All other 4 sheep remained alert, and stable hemodynamic(Figure 2)



throughout the experiment without blood transfusion . The pump flow remained unchanged(figure 2) , was 3.1+/-0.4 at hour 1 to 3.3+/-0.01 l/min day 13 against constant delta P (72.5+/-2.0 mmHg). The artificial lung blood resistance was 6-14 mHg/L/min.

The 3of 4 sheep were terminated electively day 14. Oxygen transfer and CO₂ removal from the Affinity device was 161.2+/-5.0 and 201+/-21 ml/min at hour 1 to 177+/-17 and 211+/-57 ml/min day 13 (figure 3).

Throughout the two weeks, platelet count and hematocrit remained stable without transfusion.

Conclusion: Ambulatory 2-week right heart/respiratory support is achievable with our current OxyVADsetup.