A Miniaturized Version of the Manual Single Lumen Alternating Micro-Batch (mSLAMB) Dialysis Device for Neonates

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Introduction

- Acute kidney injury is common in critically ill neonates, especially low-weight newborns. In severe cases, renal replacement therapy (RRT) may be warranted, which presents considerable technical challenges and safety issues.
- In the US, available RRT devices are cleared to a lower weight limit of 2.5 kg and require a double lumen or two separate single lumen catheters.
- Further, neonates in low-income countries often only have PD available.
- We developed a **miniaturized** manual Single Lumen Alternating Micro-Batch (mSLAMB) device (**Figure 1**), to provide clearance and ultrafiltration (UF) via one *single* lumen access for smaller patients.

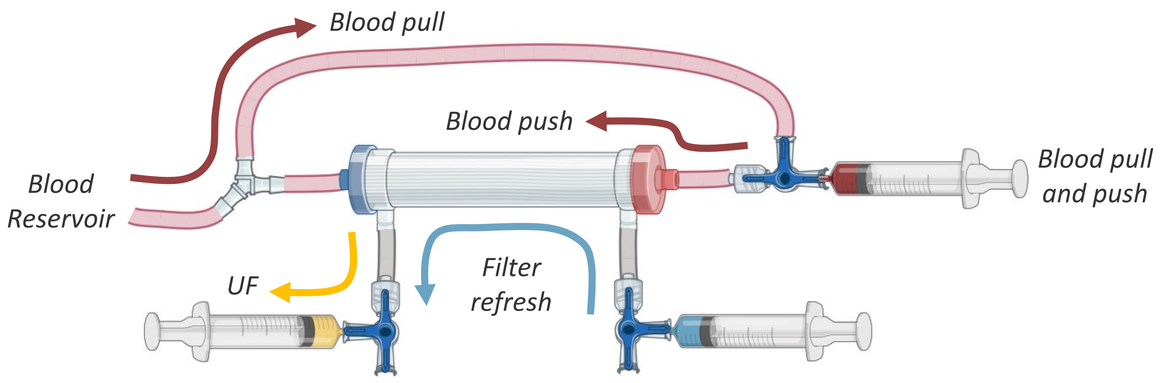

***Figure 1**. Schematic representation of the miniaturized mSLAMB device.*

Purpose

We hypothesized that **mini mSLAMB** can effectively perform clearance and UF, and that differing configurations can optimize these outcomes to propose the most efficient technique.

Methods

- We approximated a 3 kg neonate blood volume (220mL) by diluting expired packed red blood cells with 0.9% NaCl to a hematocrit (Hct) of 35%.
- Five-hundred units of Heparin and 1 g of urea (454 mg/dL) were added.
- A cycle consisted of aspirating 10 mL of blood from the blood reservoir, passing it through a hemofilter and then returning it. We conducted 2 set of experiments, the first to study ultrafiltration (UF study) and the second to test clearance performances (clearance study). Experiment details are provided in **Table 1.**

Set of experiments	Cycles per exp	Hemofilter	Hemofilter volume	Tubing volume	Outcome Measure
Ultrafiltration	60	Stavro XR11®	8mL	5 mL	Hct
Clearance	30	Polyflux 2H®	17mL	5 mL	BUN, K

UF study

- For the UF study we performed 3 experiments with the same configuration. For each cycle, 1 mL of ultrafiltrate was removed, and the Hct was measured after every 10 cycles.
- To assess ultrafiltration, we measured Hct increase, and net UF was compared to Hct increase.

Clearance study

- For clearance study, we tested 4 configurations in triplicate, with varied timing and volume of 0.9% NaCl (dialysis fluid) used to refresh the dialysis compartment
  - Configuration 1: 10mL every 5 cycles
  - Configuration 2: 10mL every 2 cycles
  - Configuration 3: 10mL every cycle
  - Configuration 4: 20mL every 2 cycles
- We measured blood urea nitrogen and potassium every 5 cycles. We calculated the urea reduction ratio (URR) and potassium reduction rate.
- Mann-Whitney U tests were used to compare the URR and potassium reduction rates of the configurations.

Results

UF study (Figure 2)

- Initial median Hct was 34.1% (IQR 1.5).
- After 60 cycles, the median Hct increased to 52.6% (IQR 1.3).
- Change in Hct was greater than expected for the volume ultrafiltered.

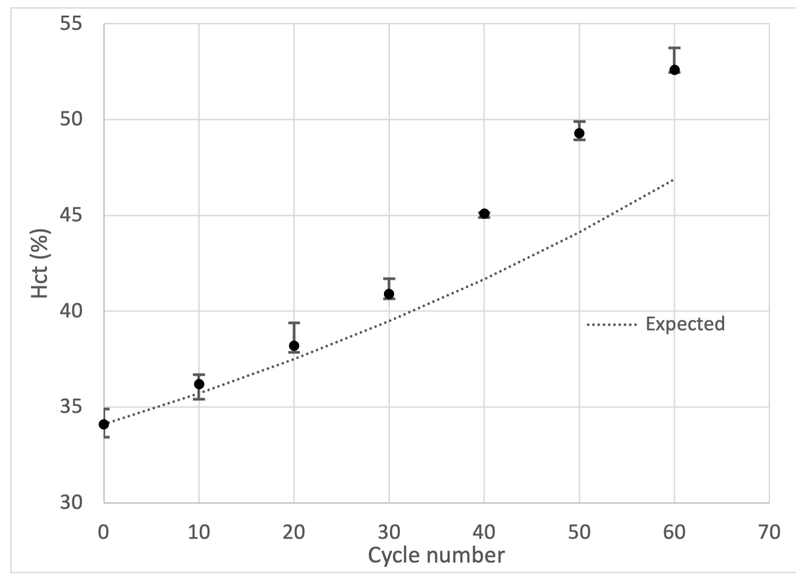

***Figure 2**. Actual vs Expected Hematocrit elevation by Cycle - median and IQR (error bars).*

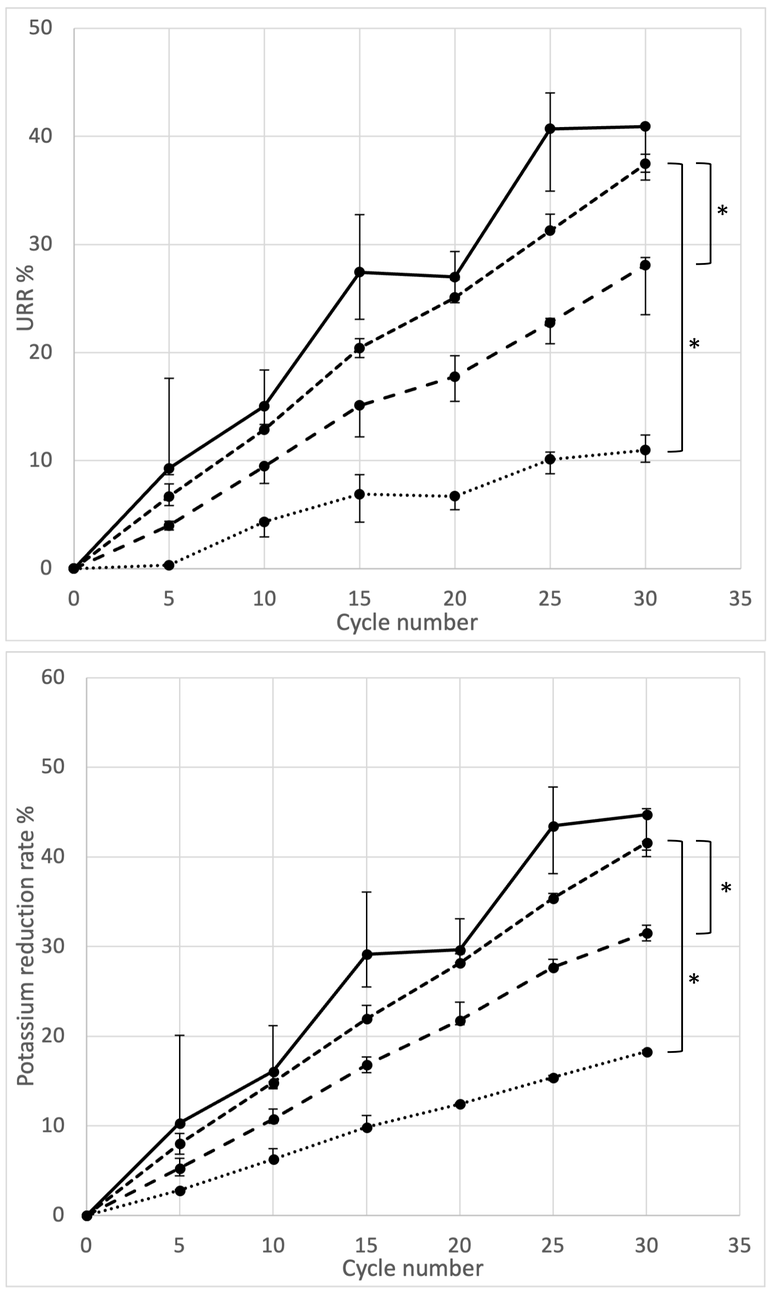

***Figure 3A, B**. URR and Potassium Reduction Rate by cycle number and configuration - median and IQR (error bars). *p-value=0.049.*

Clearance study (Figure 3A, 3B)

- After 30 cycles, median URR and potassium reduction rate was 31.0% (IQR 20.3) and 35.0% (IQR 14.7), respectively.
- Configurations 3 and 4 significantly outperformed configurations 1 and 2.

Conclusions

- The mini mSLAMB performs *in-vitro* UF and clearance efficiently.
- The discrepancy between actual and expected Hct appears to increase with greater cycle numbers. Although the exact reason for this is unknown, it is unlikely from sampling volume loss only.
- Clearance was increased with greater dialysis fluid volume to cycle ratio. Increased dialysate volume requires more dialysate but does not increase time required to complete the experiment.
- We believe the mini mSLAMB has the potential to treat neonates requiring RRT due to its minimal extracorporeal volume, efficient clearance and UF, and ability to function with single lumen access.

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