Randomized Trial of Fresh Frozen Plasma versus Albumin in Early Burn Resuscitation (NCT05069922)

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Background

- Severe burn injury results in an exaggerated inflammatory response and capillary leak that requires proper fluid resuscitation.
- Vascular endotheliopathy (glycocalyx shedding) may play an important role in pathophysiology of capillary permeability.
- Colloids such as fresh frozen plasma (FFP) and albumin are given as adjuncts to crystalloids during burn resuscitation.
- Colloids may modulate endothelial glycocalyx shedding and repair.

Objective

- To compare the safety, efficacy, and characterize endothelial effects between FFP and 5% albumin in acute burn resuscitation.

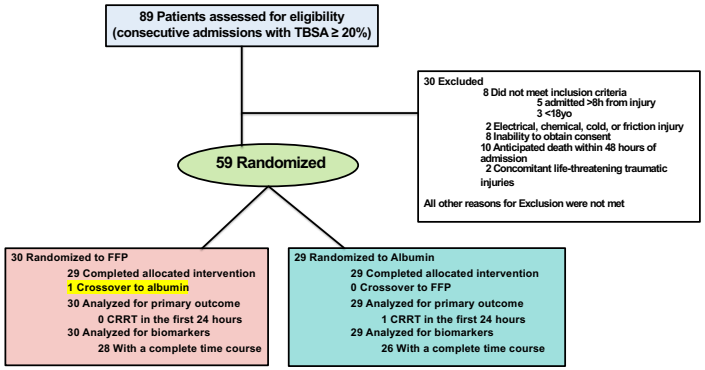
Methods

- ≥20% TBSA thermal burn patients, single center randomized trial.
- Patients resuscitated with standard Burn Center Nurse Driven Resuscitation Protocol with LR.
- Randomized to **FFP** or **5% Albumin** administered within 6-8 hours post burn injury at **0.5ml x kg x %TBSA**, given **over 8 hours**.
- All fluids (IV, carriers, tube feeds, flushes) and urine were recorded for 48 hours post-burn.
- **Primary outcome: Total fluids administered within 24 hours post burn injury**.
- Secondary outcomes:
  - Total resuscitation fluids from 25-48 hours, Intake/Output ratios (I/O)
  - Clinical complications (ARDS, AKI, transfusion reactions)
  - Presence of endotheliopathy quantified at admission, 12, 24, 48 hrs post admit using UPLC-mass spectrometry to determine circulating total glycocalyx shedding products

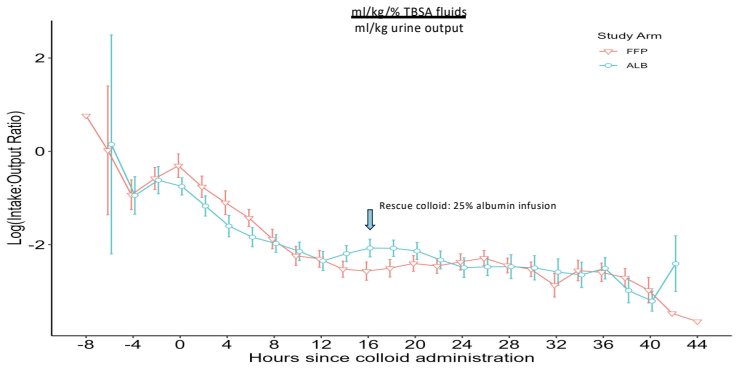
LR=Lactated Ringers; ARDS- Acute respiratory distress syndrome AKI- Acute kidney injury I/O=

Recruitment, Randomization, Results

Study Flow



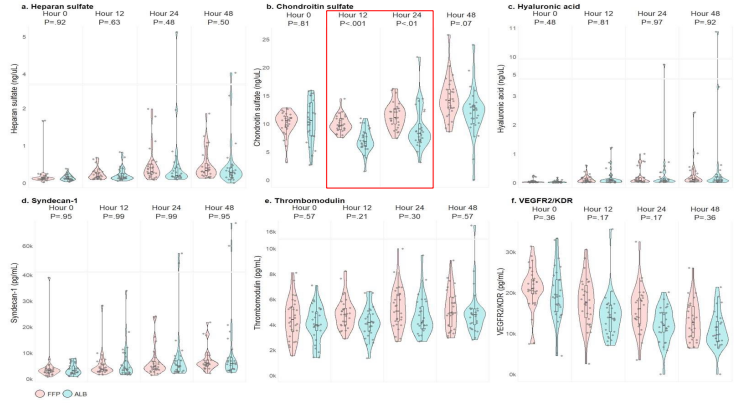
Intake/Output Ratio



Baseline Characteristics & Fluid Results

Characteristics	FFP N=30		Albumin N=29	
Age, mean (SD)	45.6 (15.2)		41.8 (15.1)	
Male	26 (86.7%)		19 (65.5%)	
Total TBSA, median (IQR)	27.9 (24.0-44.0)	Maximum 80.5%	34.5 (22.5-44.8)	Maximum 81%
TBSA 3rd degree burns, median (IQR)	18.4 (0.3-26.5)		12.0 (1.0-37.3)	
Inhalation injury	6 (20.0%)		4 (13.8%)	
Time between burn injury and admission to unit in hours, mean (SD)	4.4 (1.9)		3.9 (1.7)	
Lactate on admission, median (IQR)	3.1 (2.1-5.1)		3.4 (2.4-5.7)	
Total fluid administered in first 24 h, mL/kg/%TBSA, mean (95% CI)	5.07 (4.34 to 5.80)		4.48 (3.88 to 5.07)	p=0.2
Total fluid administered in second 24 h, mL/kg/%TBSA, mean (95% CI)	1.86 (1.49 to 2.23)		2.10 (1.77 to 2.44)	p=0.3
Time to start of study colloids post burn, hrs, median (IQR)	**8.0** (7.0-9.0)		**7.0** (5.0-7.0)	**p<0.01**
Rescue colloids in the first 24 hours post inj, No (%)	**0** (0.0)		**5** (17.2)	**p=0.02**
ARDS within 1 week, No. (%)	3 (10.0)		3 (10.3)	
Acute kidney injury (stage III), No.(%)	2 (6.7)		3 (10.3)	
Transfusion reaction	~1		0	
Mortality, No. (%)	4 (13.8)		3 (10.3)	

Endotheliopathy Analysis



Conclusions

- Total resuscitation fluid volumes were similar between FFP and 5% albumin groups when administered ~6-8 hours post burn injury.
- Clinical outcomes and complications are similar between FFP and albumin groups.
- Albumin may have a transient duration of effect compared to FFP, requiring additional colloid later.
- Endotheliopathy and glycocalyx shedding are similar in both groups, except for chondroitin sulfate levels
- Future directions: Study of colloid administration as early as possible post burn injury

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