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Starling
FLUID MANAGEMENT
MONITORING SYSTEM

FRESH SEPSIS TRIAL
DEMONSTRATES IMPROVED PATIENT OUTCOMES
When Using Dynamic Measures to Guide Fluid Decisions[1]

FRESH is the first prospective, multi-center randomized clinical trial demonstrating improved outcomes when a dynamic assessment of fluid responsiveness (PLR) is used to guide treatment in severe sepsis and septic shock patients.[1]

Decreased Fluid Balance	⬇ -1.37 L
Reduced Initiation of Mechanical Ventilation	⬇ -48%
Reduced Initiation of Renal Replacement Therapy	⬇ -12.4%
More Likely to be Discharged Home Alive	⬆ +20%

In a prospective, multi-center randomized clinical trial of 124 patients, researchers from 13 hospitals in the United States and the United Kingdom found that performing a Passive Leg Raise (PLR) before administering any clinically driven fluid bolus or increase in vasopressors, improves patient outcomes.

The intervention arm included 83 Intensive Care Unit (ICU) patients that presented to the ER with sepsis associated hypotension and anticipated ICU admission. The control arm included 41 patients that received usual care according to each institution's practice.

523 PLR assessments using the **Starling** Fluid Management Monitoring System were performed in the intervention arm. Investigators were asked to perform a PLR any time they were considering fluid administration (MAP<65, low urine output, etc). If patient was fluid responsive, fluid could be administered safely. If patient was not fluid responsive, the protocol requested that alternate treatments be prioritized over fluid.

Primary clinical outcome was fluid balance at 72-hours or ICU discharge, whichever occurred first.

The **FRESH** Prospective, Multi-Center Randomized Clinical Trial adds to the growing body of literature that supports the use of SV-guided resuscitation to improve patient outcomes that may result in a reduction in the cost of care.[1-3]

FRESH Prospective Multi-Center Randomized Clinical Trial				
	Variable	SV Guided	Control	Δ/p Value*
Primary Endpoint	Fluid Balance (Liters)	0.65 ± 2.85L	2.02 ± 3.44L	1.37L *P* = 0.021*
Secondary Endpoints	Initiation of Renal Replacement Therapy	5.1%	17.5%	12.4% *P* = 0.042*
	Initiation of Mechanical Ventilation	17.7%	34.1%	RRR=48% *P* = 0.04*
	ICU LOS (Days)	3.31 ± 3.51	6.22 ± 10.72	2.91 days *P* = 0.113
	Ventilator Use (Hours)	46.99 ± 52.33	119.42 ± 134.9	72 hours *P* = 0.079
	Pressor Use (Hours)	40.74 ± 51.23	55.64 ± 87.42	15 hours *P* = 0.426
	Change in Serum Creatinine	0.13	0.04	0.09 *P* = 0.45
Exploratory Endpoints	Discharged Home Alive	63.9%	43.9%	20% *P* = 0.035**
	30-Day Mortality	15.7%	22%	6.3% *P* = 0.388

* P value < 0.05 demonstrates statistical significance
** Not included in formal statistical testing

In conclusion, a strategy of PLR-guided resuscitation resulted in significantly lower net fluid balance and reduced renal and respiratory dysfunction at 72 hours.

The results of the study are consistent with a University of Kansas retrospective, matched, single-center study of nearly 200 patients, that was published in *Journal of Critical Care* in 2017.[2]

1. Douglas IS, et al. Fluid Response Evaluation in Sepsis Hypotension and Shock: A Randomized Clinical Trial, *Chest*. (2020), doi: https://doi.org/10.1016/j.chest.2020.04.025
2. Latham H, et al. Stroke volume guided resuscitation in severe sepsis and septic shock improves outcomes. *J Crit Care*. 2017;28:42-46.
3. Latham H, et al. Sepsis resuscitation based on stroke volume optimization improves outcome and reduces cost of care. *Crit Care Med.* 2018; 46:709.

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Baxter (India) Pvt. Ltd
5th Floor, Tower-A, Building No.9, DLF Cyber City, DLF Phase-III, Gurugram-122002, Haryana, India. Ph. +91-124-4500200 | Fax: +91-124-4263505

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