STARLING PUBLISHED STUDIES

- OVER 100 PEER-REVIEWED PUBLICATIONS
- MULTIPLE CLINICAL SETTINGS [ICU/OR/ED/EXERCISE LAB/OUTPATIENT]
- COMPARATIVE ANALYSES AGAINST ALL MAJOR TECHNOLOGIES, INCLUDING SWAN GANZ, PULSE CONTOUR, DOPPLER AND FICK

VALIDATION

The Starling system is the only non-invasive monitor that has been successfully compared to thermodilution in multiple clinical settings.


- 50 consecutive patients with Pulmonary Hypertension receiving a right heart catheterization were also monitored with the Starling system and indirect Fick.
- The study showed that the Starling system had improved accuracy and precision over Thermodilution when both devices were compared to Fick.
- The Starling system accurately detected directional changes to a vasoactive medication administration.

Study limitations: Single-site, nonrandomized, small study


- The Starling algorithm was compared to an Aortic Flow Probe in beagles. Aortic Flow Probe is the gold standard in measuring blood flow.
- In over 516 distinct measurements, the Starling system exhibited a high degree of accuracy and precision when compared with the aortic flow probe.
- This study also highlights the algorithm’s ability to handle low flow states:
  - Accuracy compared to Flow Probe: Starling system 95%
  - Precision [bias] compared to Flow Probe: Starling system 6.1% vs. Flow Probe 0.8%
  - Sufficient fidelity to detect and quantify acute, drug-induced, directional changes in CO

Study limitations: Animal study; did not use human subjects
Because IV fluids do not always help hemodynamically unstable patients and can even cause harm, it is critical to accurately predict patient fluid responsiveness in order to optimize treatment.

### ASSESSING FLUID RESPONSIVENESS


- Meta-analysis evaluating over 50 studies (2,260 patients), looking at tests to predict fluid responsiveness. This is the largest fluid responsiveness analysis to date. It did not include the **Starling** system.
- Summary fluid responsiveness is 50% (95% CI 42% to 56%). The study evaluates physical exam, CVP, Pulse Pressure Variation, IVcc, ECHO, Cardiac Output / Stroke Volume to assess fluid responsiveness.
- Physical exam and CVP cannot be used to reliably predict fluid responsiveness.
- Pulse Pressure, SV Variation, IVC work in very limited clinical conditions (require controlled ventilation).
- SV change was the best predictor of fluid effectiveness (Sensitivity 88%, Specificity 92%).

Study limitations: Meta-analysis of single-center studies; did not include randomized controlled studies


- In this Premier database analysis, 23,513 patients with severe sepsis and septic shock were admitted to the ICU from the ED.
- Day 1 fluid averaged 4.4 L, and for each liter over 5 L, mortality increased by 2.3%, and added $999 treatment cost.
- Even the small difference of 600 cc can increase the patient’s risk.

Study limitations: Hospital administration database; some limitations to data set, such as not having physiological data


- The study demonstrated that a PLR maneuver using the **Starling** system provides an accurate method of assessing volume responsiveness in critically ill patients.
- PLR results (SV+10%=Fluid Responsive) were compared to Carotid Doppler in 34 hemodynamically unstable patients.
- The PLR maneuver had a sensitivity of 94% and a specificity of 100% for predicting volume responsiveness (one false negative).
- The **Starling** system is the only non-invasive technology with a validation study evaluated during the PLR.
CLINICAL AND FINANCIAL OUTCOMES


Study limitations: Retrospective, matched, single-center study

- Retrospective matched, single-center study, SV group comprised 100 patients, with 91 patients in the UC group.
- The study demonstrated that implementing SV-guided resuscitation in patients with severe sepsis and septic shock was associated with improved patient outcomes.
  - Reduced Fluid Balance and reduced time on Pressors
  - Reduced Length of Stay (2.89 Days)
  - Decreased need for Mechanical Ventilation (25%) and Acute Dialysis (13.25%)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Starting Stroke Volume Fluid Therapy (n=100)</th>
<th>Usual Care (Control, n=91)</th>
<th>Δ/p Value</th>
<th>Costs Assumptions</th>
<th>Cost Avoidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU LOS (Days)</td>
<td>5.98 ± 0.68</td>
<td>8.87 ± 1.18</td>
<td>2.89 days $P = 0.03$</td>
<td>$4,004/ICU day $906/floor day$</td>
<td></td>
</tr>
<tr>
<td>Fluid Balance (Liters)</td>
<td>1.77 L ± 0.60</td>
<td>5.36 L ± 1.01</td>
<td>3.59 L $P = 0.002$</td>
<td></td>
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<tr>
<td>Pressor Use (Hours)</td>
<td>32.08 ± 5.22</td>
<td>64.86 ± 8.39</td>
<td>32.78 hours $P = 0.001$</td>
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</tr>
<tr>
<td>Mechanical Ventilation (Relative Risk)</td>
<td>29%</td>
<td>57%</td>
<td>RR=0.51 $P = 0.001$</td>
<td>$1,522/day $5.1 days$</td>
<td>$1,940</td>
</tr>
<tr>
<td>Acute Dialysis Therapy Initiated</td>
<td>6.25%</td>
<td>19.5%</td>
<td>13.25% $P = 0.01$</td>
<td>$27,182 x (lc)$ [12.73 cases avoided/96 total patients]</td>
<td>$3,605</td>
</tr>
</tbody>
</table>

**ESTIMATED SAVINGS PER TREATED PATIENT** $14,498

*Based upon supplemental data.

**COST ASSUMPTIONS**

**ICU Length of Stay (LOS):** 2.89 days x ($4,004 [Avg ICU Day] – $906 [Avg Floor Day]) = $8,953

**Mechanical Ventilation (MV):** $1,522 x 5.1 days x .25 = $1,940

Assumes:
1. Incremental cost of MV $1,522/day.
2. Average duration of MV in septic shock 5.1 days.
3. An absolute 25% reduction of patients receiving mechanical ventilation.

**Acute Dialysis Therapy:** $27,182 x (lc) [12.73 cases avoided/96 total patients] = $3,605

REFERENCES


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