Active Clearance of Chest Tubes with the ClearFlow, Inc. “PleuraFlow” System

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Disclosures

Adagio Medical, Inc. – Laguna Hills, CA

Atricure, Inc. – Mason, OH

ClearFlow, Inc. – Anaheim, CA

Harpoon Medical, Inc. – Baltimore, MD

PAVmed, Inc. – NYC, NY

PotentiaMED, Inc. – St. Louis, MO

SentreHEART, Inc. – Palo Alto, CA
Current Problems with Chest Tube Drainage
Incidence of chest tube clogging after cardiac surgery: a single-centre prospective observational study.


(Cleveland Clinic)

- **36%** of chest tubes clog
- **86%** occlude below the skin
Impact of retained blood requiring reintervention on outcomes after cardiac surgery


n = 6,909 patients

- **In-Hospital Mortality** - Increased from 4% to 20%
- **Acute Renal Failure** – Increased from 10% to 42%
- **ICU Stay** – Increased from 2 days to 8.3 days
- **Hospital Stay** - Increased from 12 days to 26 days
- **Mortality Rate** – Increased from 3.7% to 8.3%
- **Deep Sternal Wound Infection** – Increased from 2.2% to 6.7%
- **Composite of MAE’s** – Increased from 6.9% to 21%
- **Incremental Cost (Unadjusted)** – 23,376 Euros
- **Incremental Cost (Adjusted)** – 15,278 Euros
Improved Chest Tube Drainage System
Tamponade Relief by Active Clearance of Chest Tubes

Vistarini N, Gabrysz-Forget F, Beaulieu Y, Perrault LP

*Ann Thorac Surg.* 2016;101:1159-1163

(Montreal Heart Institute)
PleuraFlow
ACT System

- Magnetic Drive
- Sterile environment
PleuraFlow
ACT System

- Magnetic Drive
- Sterile environment
PleuraFlow
ACT System

- Magnetic Drive
- Sterile environment
Active Clearance of Chest Drainage Catheters Reduces Retained Blood

Sirch J, Ledwon M, Puski T, Boyle EM, Pfeiffer S, Fischlein T.

(Nurenburg, Germany)

• n = 2,105 patients
• 43% reduction in retained blood
Results of Improving Chest Tube Drainage
Meta Analysis Establishes Level 1A Evidence That Reducing Retained Blood in Pericardium Decreases Postop Complications

(Meta-analysis of 3,425 patients)

- 90% reduction in Tamponade
- 80% reduction in Pericardial Effusions
- 1 day reduction in Length of Stay
- 50% reduced Mortality
- 58% reduction in POAF

POAF following Cardiac Surgery

- **Invulnerable to POAF**
  - 65% No AF

- **Vulnerable to POAF**
  - 35% POAF

- **Always have POAF**
POAF following Cardiac Surgery

Invulnerable to POAF

Vulnerable to POAF

30% Treatable

Always have POAF
Chest Drainage Using Active Clearance Technology Reduces the Incidence of Postoperative Atrial Fibrillation.


\[ n = 300 \text{ patients} \]

- 142 with ACT Drainage
- 157 with Conventional Drainage

• **Unmatched Patients:** 34% reduction in POAF (35% to 23%)
• **Matched Patients:** 31% reduction in POAF (35% to 24%)
Active Clearance of Chest Drainage Catheters Reduces Retained Blood


N = 2,105 patients

- 33% reduction in POAF (30% to 20%)
Evidence that Reducing Retained Blood Decreases POAF following Cardiac Surgery

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>AF Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sirch (2016)</td>
<td>2,105</td>
<td>33%</td>
</tr>
<tr>
<td>Gozdek (2017)</td>
<td>3,425</td>
<td>58%</td>
</tr>
<tr>
<td>St. Onge (2017)</td>
<td>300</td>
<td>31%</td>
</tr>
</tbody>
</table>
Impact of Retained Blood on Hospital Costs
Postoperative atrial fibrillation significantly increases mortality, hospital readmission, and hospital costs

LaPar DJ, Speir AM, Crosby IK, Fonner Jr E, Brown M, Rich JB, Quader M, Kern JA, Kron IL

49,264 patients in STS-approved Virginia Database

• Mortality - Increased from 1% to 2% (p<0.001)
• ICU Stay – Increased by 48 hours (p<0.001)
• Hospital Stay – Increased by 3 days (p<0.001)
• Mortality Rate – Increased from 3.7% to 8.3%
• Incremental Cost – $12,000
Cost of Retained Blood (US Data Sources)

313,766 US Adult Cardiac Surgery Patients\(^1,2\)
\(\Delta + \$28,814\) for every RBS patient
17% RBS Incidence

234,555 US Adult Cardiac Surgery Patients\(^3,4\)
\(\Delta + \$23,400\) for every RBS patient
14% RBS Incidence

1. Based on over 313,000 US adult heart surgery patients. Data extracted using ICD-9 codes from the 2010 Nationwide Inpatient Sample (NIS), from the DHHS Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project (HCUP).

2. At discharge, both Billing Charges and Cost of Care were 55% higher for patients who had one or more RBS interventions. Cost of Care = Charges \times 2010\text{ Ratio of Cost To Charge (RACC)}\text{ Rate of 35.4%}.

3. Based on over 234,000 US adult heart surgery patients followed through hospital discharge. Data was extracted using ICD-9 codes from the 2013 MarketScan\textsuperscript{\textregistered} PIDB and Commercial Medicare Databases. Data collected by Truven Health Analytics, an IBM Company.

4. Mean costs at discharge (charges were $254,022 for patients with RBS interventions; $169,635 without RBS).
## Increased Hospital Costs due to Retained Blood following Cardiac Surgery

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Increased Cost/Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>LaPar (2014)</td>
<td>49,264</td>
<td>$12,000</td>
</tr>
<tr>
<td>NIS (2015)</td>
<td>313,766</td>
<td>$28,814</td>
</tr>
<tr>
<td>Mkt Scan (2015)</td>
<td>234,555</td>
<td>$23,400</td>
</tr>
<tr>
<td>Balzer (2016)</td>
<td>6,909</td>
<td>15,278 Euro</td>
</tr>
</tbody>
</table>
### Cost Savings using the PleuraFlow ACT System

<table>
<thead>
<tr>
<th>Cardiac Surgery Procedures/year</th>
<th>1,200</th>
<th>800</th>
<th>400</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate of RBS Complications @ 17%&lt;sup&gt;1&lt;/sup&gt;</td>
<td>204</td>
<td>136</td>
<td>68</td>
</tr>
<tr>
<td>Cost of RBS Complications&lt;sup&gt;1,2&lt;/sup&gt;</td>
<td>$5,878,056</td>
<td>$3,918,704</td>
<td>$1,959,352</td>
</tr>
<tr>
<td>42% Reduction&lt;sup&gt;3&lt;/sup&gt;</td>
<td>$2,468,784</td>
<td>$1,645,856</td>
<td>$822,928</td>
</tr>
<tr>
<td>Cost of ACT&lt;sup&gt;4&lt;/sup&gt;</td>
<td>$474,000</td>
<td>$316,000</td>
<td>$158,000</td>
</tr>
<tr>
<td>Projected Hospital Savings</td>
<td><strong>$1,994,784</strong></td>
<td><strong>$1,329,856</strong></td>
<td><strong>$664,928</strong></td>
</tr>
</tbody>
</table>

<sup>1</sup> Based on over 313,000 US adult heart surgery patients from the 2010 Nationwide Inpatient Sample (NIS)/(AHRQ)/(HCUP).

<sup>2</sup> $28,814 average cost per patient who had 1 or more RBS complications that required re-operation or intervention

<sup>3</sup> Clinical trial results Sirch, JTCVS, 2016

<sup>4</sup> $395 per PleuraFlow ACT System
• Chest tube clogging and retained blood are common problems following cardiac surgery.

• Retained blood increases postoperative complications, causes poorer outcomes, and increases hospital costs for cardiac surgery.

• More effective clearance of retained blood following cardiac surgery reduces postoperative complications, including POAF.

• The PleuraFlow Active Clearance Technology (ACT) is effective in evacuating retained blood and results in improved outcomes and increased hospital profits following cardiac surgery.
Thank You