MIST
Minimally-invasive Infusion & Suction Therapy Device

Effective treatment for deadly abdominal trauma and sepsis
Summary

• Medical device for treating condition that annually kills ~156k intensive care unit (ICU) patients in US
• Annual US market: $180-$600 million
• Developed over five years by team led by respected critical care research scientist
• Patent applications pending in US and EU
  – Positive international search report
• Non-competitive predicate devices on market should smooth path to regulatory approval
Abdominal compartment syndrome

• A serious clinical problem:
  – Afflicts 240,000/yr in US alone; 65-85% or >156,000 die/yr
  – Caused by blunt abdominal trauma, hemorrhagic shock, massive fluid resuscitation, burns, rising abdominal pressure
  – Defined as high intra-abdominal hypertension (IAH) >20mm Hg plus at least one organ in failure
  – “If left untreated, abdominal compartment syndrome is almost uniformly fatal.”¹

• Abdominal compartment syndrome (ACS) accounts for:
  – 50-80% of deaths in ICU
  – ~40% of ICU bed days
  – Approximately half of all ICU costs

¹ http://emedicine.medscape.com/article/829008-overview#aw2aab6b2b5
ACS is deadly – 3rd party study results

- Study “Incidence and clinical effects of intra-abdominal hypertension in critically ill patients”¹
  - 83 patients admitted to the ICU
  - 64% had or developed intra-abdominal hypertension (IAH)
    - 31% had IAH on admission
    - 33% developed IAH during their stay
  - 12% developed ACS

- Results: High mortality
  - 43% mortality among those with IAH (28% or 23 patients)
  - 80% mortality among those with ACS (10% or 8 patients)

Underlying Cause of ACS

• Excessive systemic inflammation, usually caused by abdominal trauma/surgery or burns, which... over activates the body’s inflammatory response leading to the... collection of toxic inflammatory fluids (ascites$^1$) in the peritoneal cavity of the abdomen which... exacerbates the primary injury and reinforces the body’s systemic inflammatory response... resulting in organ damage, failure, and/or death

$^1$ Ascites is a gastroenterological term for an accumulation of fluid in the peritoneal cavity. They contain inflammatory mediators.
ACS’s Deadly Cycle

Inflammation

\[ \Delta \text{MicroQ} \]

\[ \uparrow \text{Vas Perm} \]

Toxic Ascites

Underlying Disease State

More Toxic Ascites

\[ \uparrow \text{IAP} \]

\[ \downarrow \text{LymphQ} \]
Current treatment for ACS is ineffective

• Decompressive laparotomy – “the gold standard”\textsuperscript{1}
  
  – Large incision through the abdominal wall
    • Typically a midline incision: sternum (xiphoid process) to navel
    • “Current treatment of patients with ACS is urgent decompressive laparotomy, either in the operating room or at the bedside...The peritoneal cavity is usually left open postoperatively, and the exposed contents are covered with a sterile dressing such as an iodine impregnated plastic adhesive drape.”\textsuperscript{2}
  
  – Laparotomies have a high incidence of adverse events (e.g., deaths)
    • >50% of ACS patients die despite laparotomy
    • Unfortunately, once ACS is well advanced, surgical decompression may have serious adverse effects resulting in massive washout of anaerobic products, profound hypotension, and asystolic arrest.”\textsuperscript{2}

• The current alternative is almost certain death

Proposed ACS Treatment: MIST Device

• Minimally-invasive device that prevents or treats ACS by suctioning out toxic ascites, and infusing cleansing and treatment fluids into the peritoneal cavity
  – Consists of small-diameter plastic assembly with suction and injection ports at one end, and manifold with multiple catheters attached at the other

• Surgically deployed into the abdomen through a small laparoscopic incision (0.5-1.5 cm)
  – Drain catheters are placed in peritoneal gutters (low points) laparoscopically

• Cleansing & treating fluid includes dialysis fluid & antibiotics

• Inserted prior to ACS developing
Minimally-invasive mitigating Infusion & Suction Therapy

Deployed preemptively (preferably before ACS develops) to:

1. Suction out toxic ascites fluids and relieve intra-abdominal pressure,
2. Infuse cleansing and treatment fluids into peritoneal cavity, to treat infection and reduce inflammatory response,
Experimental support

• Upstate large animal study confirms\(^1\):
  – Presence of ascites is causal factor in morbidity
  – Removal of ascites dramatically reduces morbidity

• Peritoneal dialysis\(^2\) demonstrates safety and benefit of infusing dialysis fluid into abdomen

• Planned:
  – Study to test whether preemptively using a MIST device to remove ascites, and cleanse and treat the peritoneal cavity, reduces the onset of ACS and morbidity from IAH (intra-abdominal hypertension)

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\(^1\) Peritoneal negative pressure therapy prevents multiple organ injury in a chronic porcine sepsis and ischemia/eperfusion model, Shock Augusta Ga (2010), Volume: 34, Issue: 5, Pages: 525-534. PubMed: 20823698. This paper swept awards at World ACS meeting in 2010.

\(^2\) An alternative to hemodialysis. Dialysis fluid is introduced through a permanent tube in the abdomen and flushed out every night.
Business Case

• US market size: > $180-$600M/yr in US alone at price point of $750/MIST device¹

• Market need: use will shorten hospital stays, lower treatment costs, and reduce mortality

• FDA approval: predicate devices already on market should smooth path (predicates are obvious but not competitive)

• Product extensions through development of cleansing & treatment compositions possible

¹ Low end assumes only ACS patients treated; high end assumes all patients diagnosed with IAH are treated. As it is expected that treatment with MIST will be indicated by an intra-abdominal pressure (IAP) less that the 12 mm Hg characterizing IAH, the market for the MIST device should actually be significantly larger.
MIST

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