FluidAI's Stream™ Platform for Monitoring for Leak in Post-Esophagectomy Patients: Preliminary Results from a Pilot Clinical Trial

MICHIGAN MEDICINE
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Objective

- Anastomotic leaks are a serious complication following esophagectomy, occurring in **10-25% of patients.**
- Risk factors include **poor conduit blood flow and neck anastomosis.**
- Leaks are associated with increased morbidity, a **7-35% mortality rate, and increased costs/utilization.**
- **Early diagnosis** of potential anastomotic leaks is critical.

Hypothesis: Measurement of postoperative drainage fluid biomarkers can enable early prediction of anastomotic leak following esophagectomy.

Technology Description

- FluidAI's Stream™ Platform is a portable, non-invasive biosensor system that attaches inline between standard drainage catheters and evacuator bulbs.
- It is designed to monitor real-time changes in drainage effluent characteristics, specifically pH and electrical conductivity (EC), via the Origin™ hardware component.
- The measurements conducted by Origin™ are displayed and stored on tablets known as Delta™ Monitors through the Stream™ App.
- This pilot study aims to evaluate the safety and useability of Stream™ Platform and track pH and EC trends in esophagectomy patients. We will also assess if FluidAI's existing algorithm for leak prediction(which were developed based on intraperitoneal bowel anastomosis data) translates to esophagectomy leak prediction.



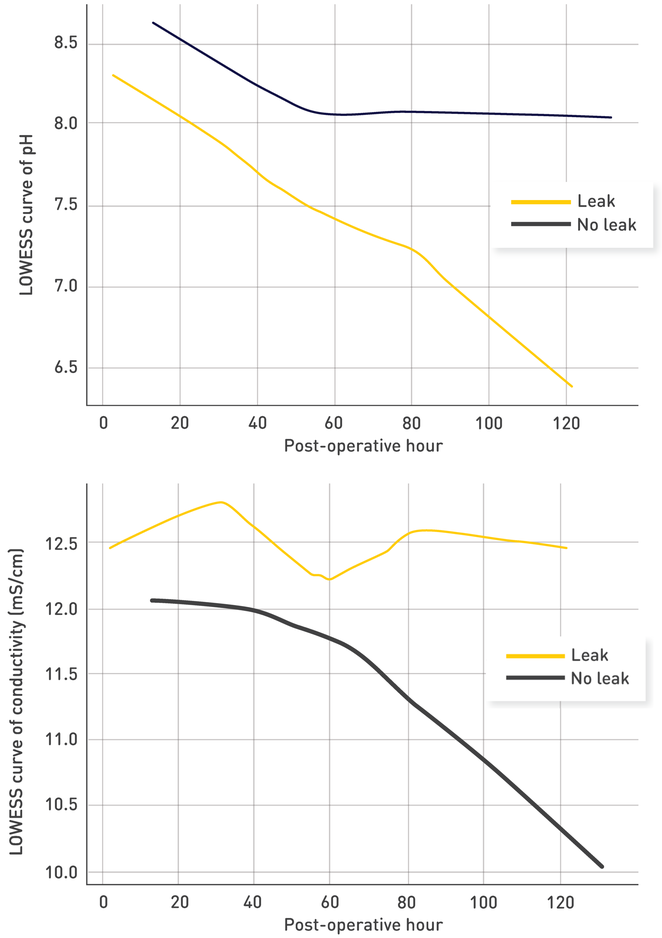
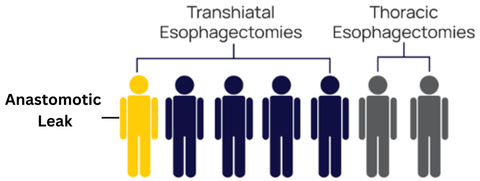


Figure 1: Trends in pH (top) and electrical conductivity (bottom) over time in one patient with anastomotic leak versus six patients with no anastomotic leak

Preliminary Results

- To date, **7 patients** have been evaluated with the platform. 5 patients received transhiatal esophagectomies and 2 had transthoracic approaches. All had drains placed at the anastomosis. One of the transhiatal patients developed an anastomotic leak.



- Devices were attached on postoperative day 0 or 1, on average at postoperative hour (POH)-17 and detached at POH-92 (average length of attachment: 75 hours).
- The patient diagnosed with a leak demonstrated an average pH of 7.44 and an average EC of 11.82 mS/cm. The 6 patients who did not experience an anastomotic leak demonstrated an overall average pH of 7.96 and an overall average EC of 11.12 mS/cm. Dynamic trends in pH and EC were captured over time (Figure 1).
- **There have been no safety concerns associated with the Stream™ Platform.** There was one instance of Origin™ pH and EC sensor calibration issues, and the device was removed approximately 48 hours after attachment. Formal statistical comparison has not yet been performed due to low sample size.

Conclusions and Future Directions



- Electrical conductivity and pH may be early predictors of post-esophagectomy anastomotic leaks, with similar trends (lower pH, higher EC) to that of intraperitoneal bowel anastomotic leaks.
- Data collection is ongoing with continued assessment of safety and device use optimization in esophagectomy patients. FluidAI's Stream™ Platform is a novel system that may help surgeons better manage postoperative complications after esophagectomy.