Continuous Drain Monitoring of pH and Electrical Conductivity Enables Early Detection of Anastomotic Leaks: Results from a Multi-Center Feasibility Study

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Introduction

Clinical significance of anastomotic leaks

Anastomotic leaks (AL) are among the most serious complications following hepatobiliary (HPB), colorectal, and upper gastrointestinal (UGI) surgery, contributing to **increased morbidity, mortality, and healthcare costs.**

- AL often triggers a cascade of secondary life-threatening complications, including **intra-abdominal abscesses, sepsis, peritonitis, hemorrhage, and multi-organ failure**. It also increases the risk of needing a **permanent stoma or major reoperation.**
- Patients who develop a leak experience **significantly prolonged hospital length-of-stay, higher readmission rates, and frequent unplanned ICU admissions.** This prolonged care and need for reintervention impose a massive financial strain on healthcare systems.

Limitations of current detection methods

- Current detection methods rely primarily on clinical symptoms, laboratory markers, and radiologic imaging.
- These approaches typically identify leaks **only after significant physiological deterioration has occurred.**
- As a result, diagnosis often occurs several days after the leak begins, **limiting opportunities for early intervention.**

Role of continuous physiological monitoring

- Early biochemical changes may occur before overt clinical symptoms develop.
- Continuous monitoring of peritoneal drain fluid may provides a real-time, objective assessment of the anastomotic site.
- Continuous monitoring captures brief but clinically relevant fluctuations in biomarkers that might otherwise be missed.
- Origin™ continuously measures the pH and electrical conductivity (EC) of drainage fluid:
  - **pH**, which may decrease in response to inflammation and tissue ischemia.
  - **EC**, which may increase due to inflammatory changes and ion accumulation in drainage fluid.

Study rationale

Continuous monitoring of peritoneal fluid biomarkers, such as pH and electrical conductivity, captures early physiological changes associated with AL development that traditional reactive methods often miss.

Integrating this real-time sensor data with patient-specific clinical variables into a predictive model may allow for the identification of high-risk patients days earlier than standard-of-care, supporting a critical shift toward proactive clinical management and more timely, less invasive interventions.

Objectives and Design

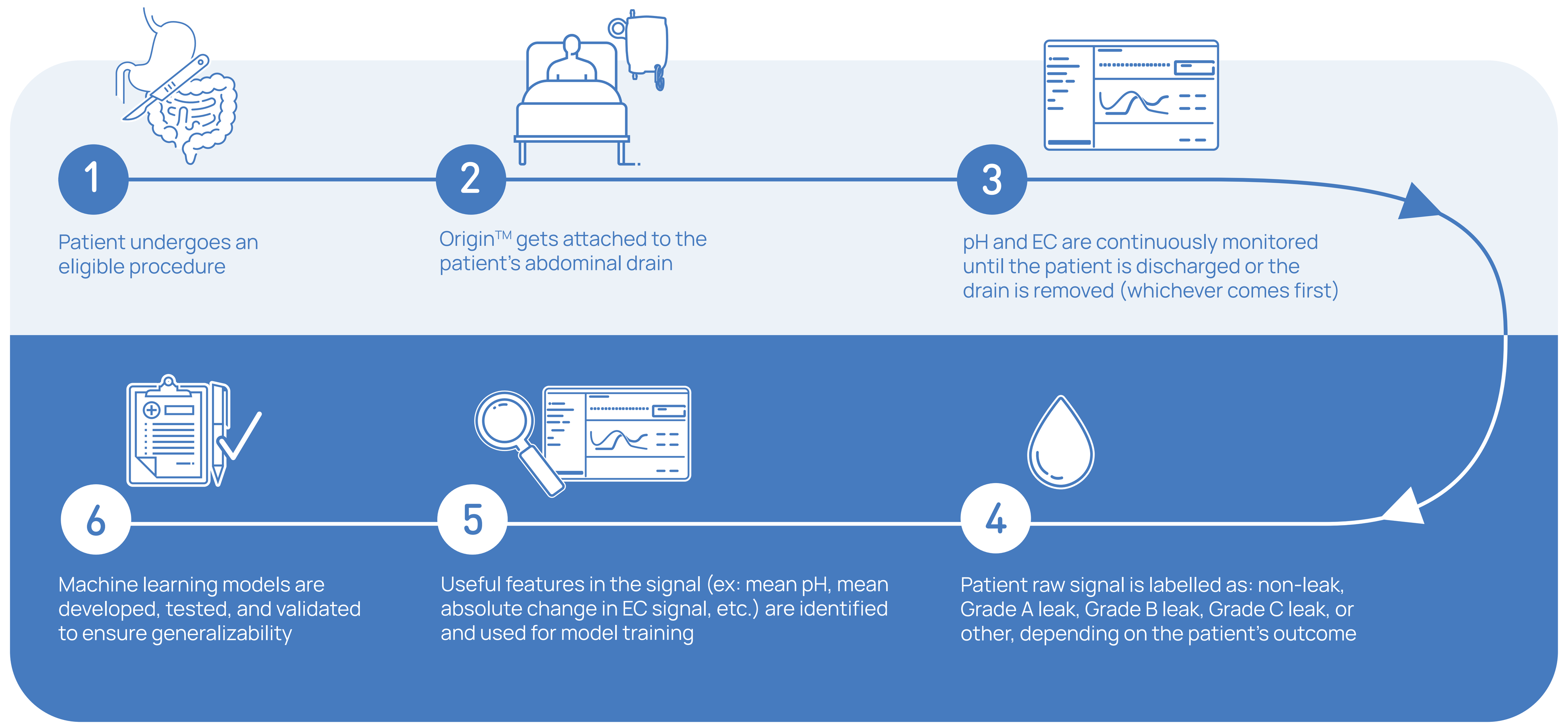
Primary Objectives

1 Observe the change in pH and EC of abdominal drainage fluid in the event of an anastomotic leak.

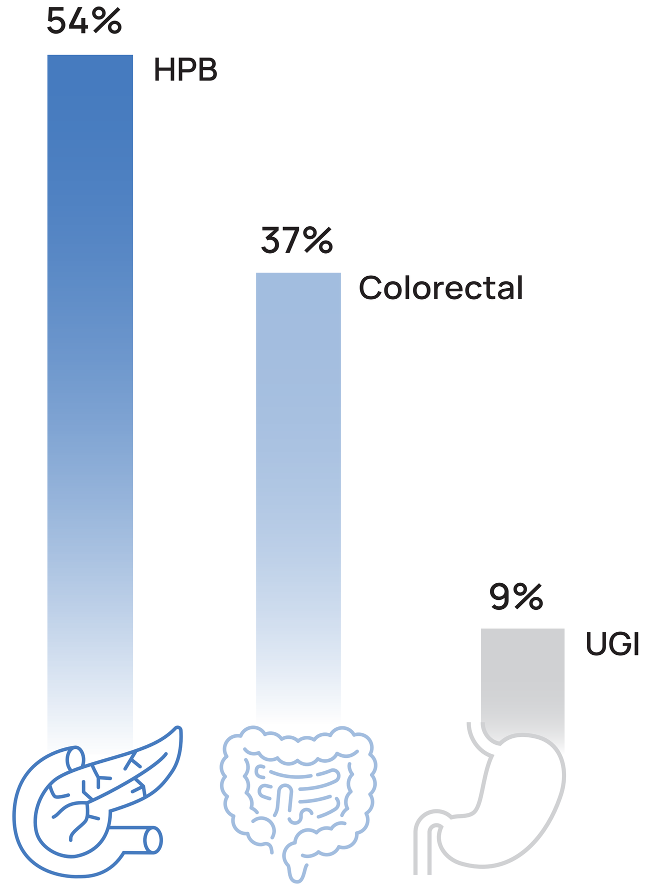
2 Develop a clinical prediction model based on continuous biomarker data collected using FluidAI's inline monitoring device (Origin™).

3 Evaluate whether predictive model performance differs across surgical patient populations, including HPB, colorectal, and UGI cohorts.

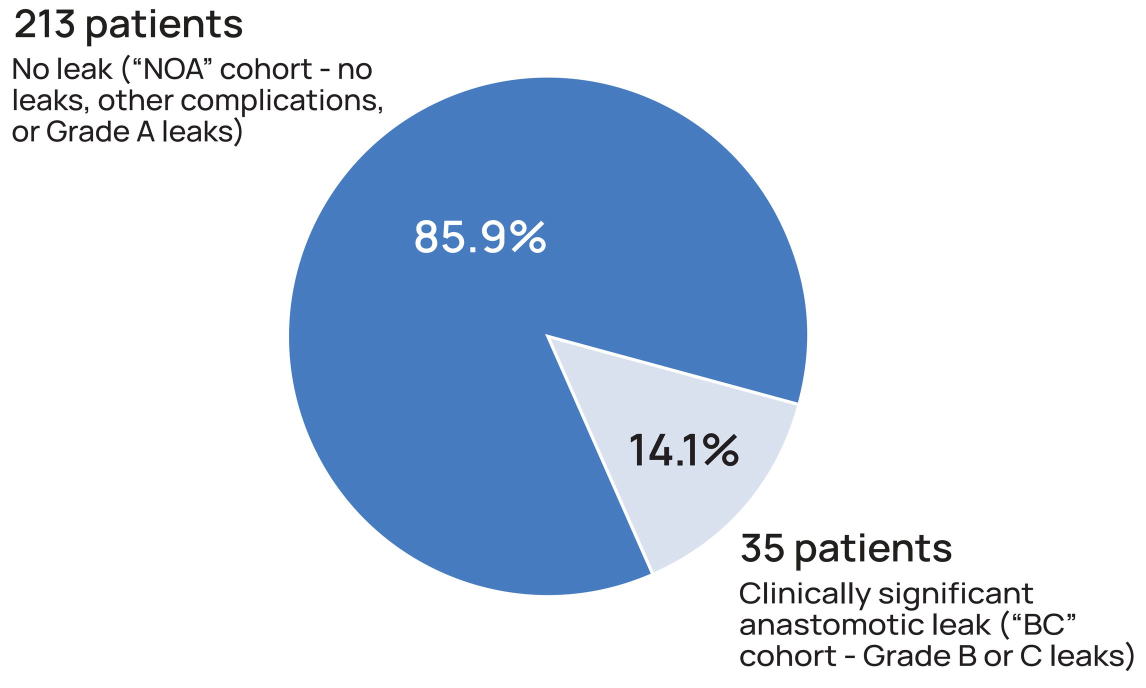
Study Design & Workflow



Study Population



Anastomotic Leak Incidence



AL was defined according to International Study Group criteria (ISGPS 2016; ISREC 2010). Controlled Grade B leaks (Archer et al., 2021) were not considered clinically significant.

Results

Biomarker Trends: pH and Electrical Conductivity

- Continuous monitoring of drainage fluid revealed distinct biochemical patterns in patients who developed anastomotic leaks:
  - Leak patients demonstrated consistently lower pH values in postoperative drainage fluid compared with non-leak patients.
  - Leak patients also showed higher EC levels.

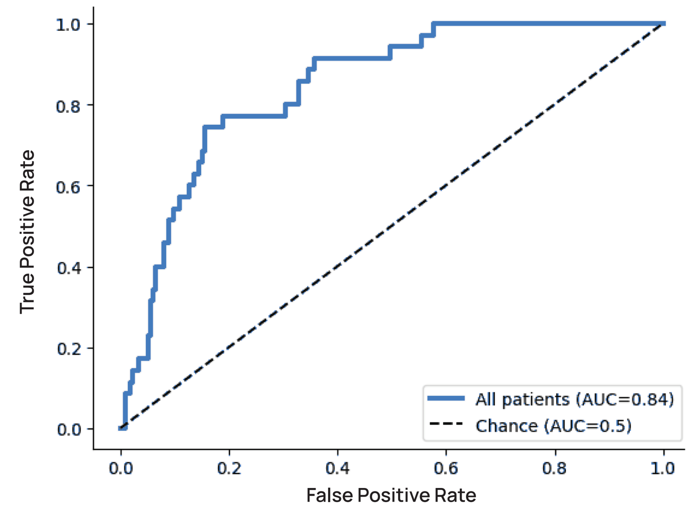
Predictive Model Performance

- Various machine learning models (Random Forest, Support Vector Machine, Logistic Regression, and Gaussian Naïve Bayes) were tested to determine the optimal approach for predicting anastomotic leaks.
- A machine learning model was successfully developed using exclusively data from the first 48 postoperative hours. The model relies on a combination of continuous sensor data and standard clinical metrics:

Mean pH (post-op hour (POH) 0-24)	Mean absolute change in pH (POH 0-48)	Mean absolute change in EC (POH 0-24)	Mean Pulse (POH 0-24 and 24-48)	ASA classification	Transfusion status	BMI	Age

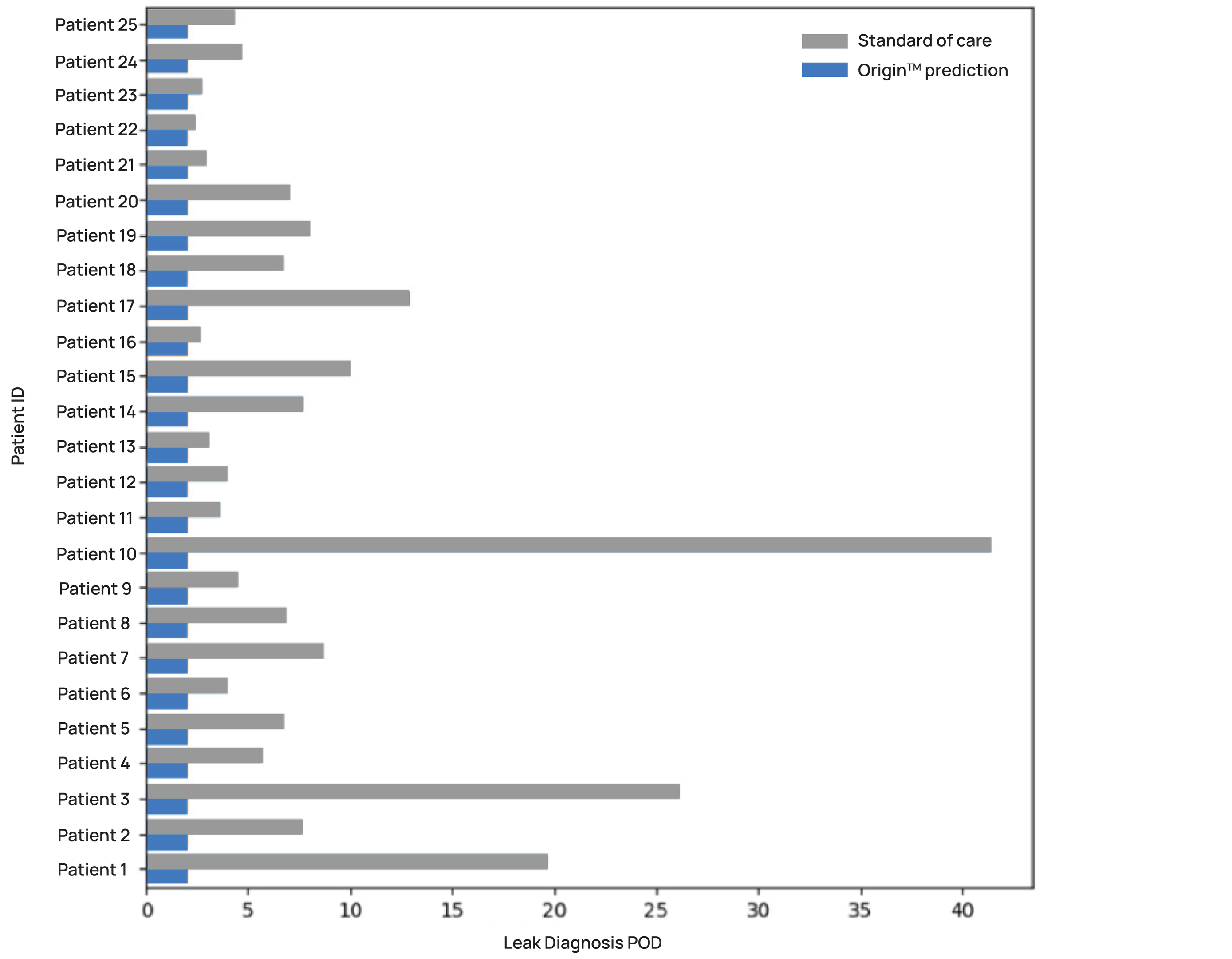
- Model performance for the overall cohort and relevant sub-cohorts is summarized below:

Metric	All	HPB	Colorectal	UGI
Accuracy	83.1%	73.9%	96.7%	86%
Balanced accuracy	79.4%	72.5%	98.3%	90%
Sensitivity	74.3%	70%	100%	100%
Specificity	84.5%	75%	96.6%	80%
AUC	84.4%	76.1%	98.9%	83.3%



Time to AL Detection

- Standard-of-care methods detected AL at a median of 8.6 days postoperatively.
- Model prediction was generated at postoperative day 2.
- This suggests the potential for identification of AL up to ~6.6 days earlier than the standard-of-care.



Economic Impact

- Anastomotic leaks were associated with substantial healthcare resource utilization.
- Leak patients had a longer mean length of stay than non-leak patients (18.5 ± 14.8 vs 7.5 ± 6.1 days).
- Leak patients experienced higher rates of secondary postoperative complications, including significantly increased abdominal abscess ($p < 0.001$) and sepsis ($p = 0.038$).
- Presence of a clinical leak was associated with a 65% increase in median healthcare costs ($p < 0.001$).

Conclusions

Continuous monitoring of drainage fluid biomarkers (pH and electrical conductivity) using Origin™ enables early identification of physiological changes associated with anastomotic leaks.

Predictive modelling achieved strong discrimination (AUC 0.84; accuracy 83%) with model outputs available by postoperative hour 48, several days earlier than leak detection by standard of care.

Earlier identification of AL risk may enable more timely intervention, improved patient outcomes, and reduced healthcare costs, highlighting the value of continuous monitoring technologies.