Early Detection of Colorectal Anastomotic Leaks using a Non-Invasive, Inline Drainage Fluid pH and Conductivity Monitor

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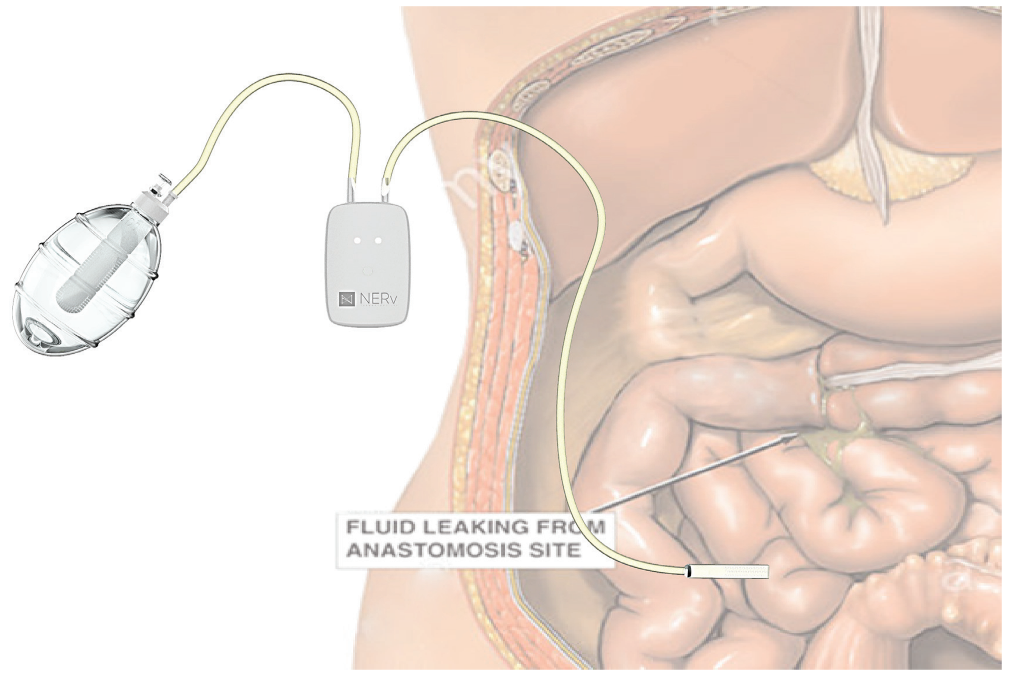
Introduction

Colorectal anastomotic leakage (CAL) is regarded as a major postoperative complication of colorectal surgery, impacting nearly 6-30% of patients.[1] CAL greatly increases the risk of peritonitis, abscess formation, and sepsis.[1] Early diagnosis of CAL is critical for reduction of morbidity and mortality.[1] Presently, no reliable method exists for the early detection of CAL. [3] The current standard of practice for the diagnosis of CAL has limited sensitivity and can be nonspecific.[3] Previous investigations have highlighted the role of low local pH as a biomarker for early detection of CAL.[1,2]



This study aims to illustrate the efficacy of a novel wireless and continuous monitoring device developed by NERv Technology Inc. The device measures pH and electrical conductivity of peritoneal drain effluent as pathophysiological biomarkers to allow for the early detection of iatrogenically produced CAL in a porcine model.

Method

16 Yorkshire Swine (mean age of 3.9 months and mean weight of 30.5 kg)

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Enterotomy of Descending Colon with End-to-End Anastomosis and Exteriorization of Suture for Postoperative Pull-out

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Attachment of NERv's Inline Device to Jackson-Pratt ® Silicone Catheter Placed near the Anastomosis

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n=10 → CAL Group: Suture Line Compromised

n=6 → Control Group: Suture Line Intact

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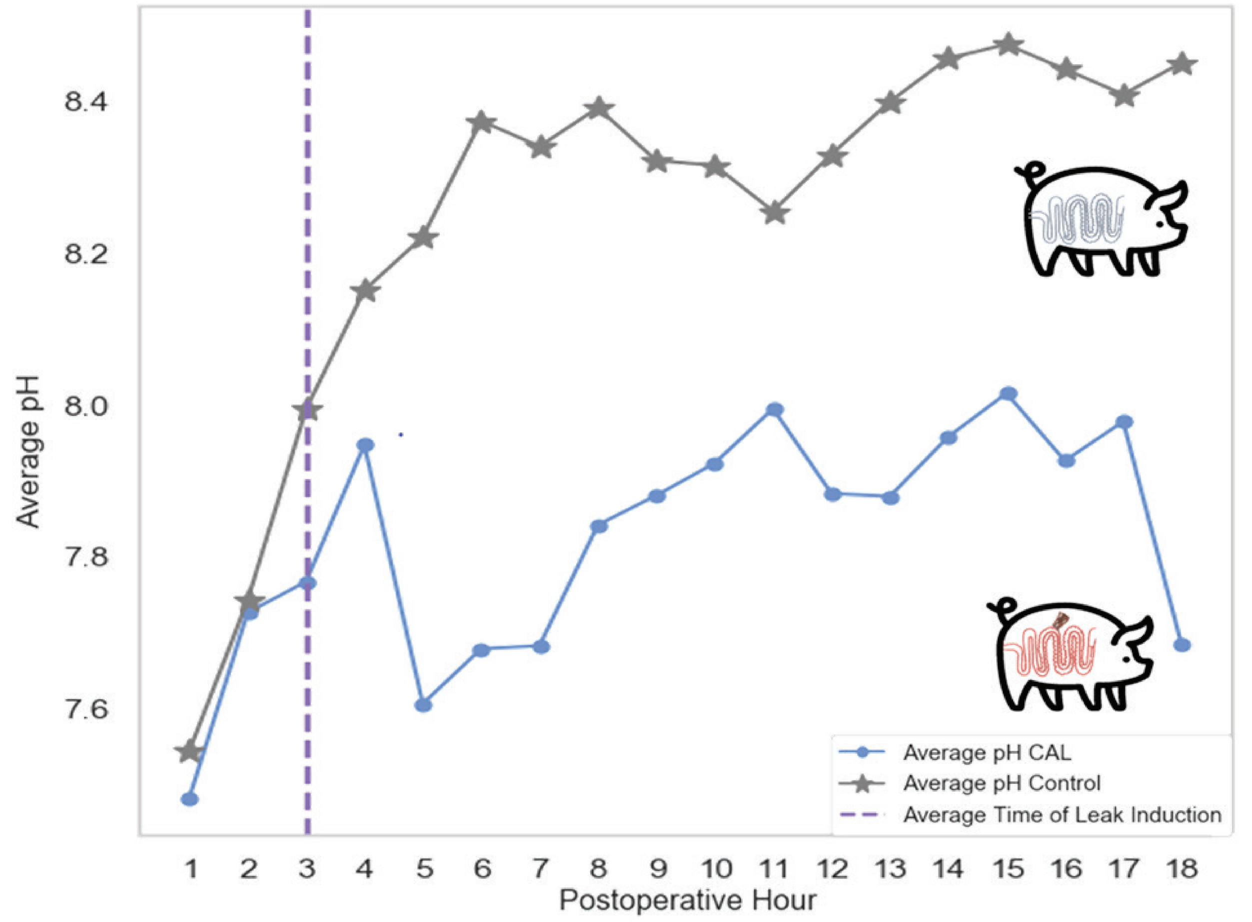
Continuous Monitoring of pH and Electrical Conductivity of Postoperative Drainage for up to 5 Days or until Clinical Manifestation of CAL

State of abdominal cavity as seen during exploratory laparotomy in (A) CAL group showing enteric spillage, and in (B) Control group showing intact anastomosis and no local signs of CAL.

Results

Animals in CAL group showed clinical symptoms (lethargy, tachypnea, etc.) of leakage at postoperative hour (POH) 28 on average, while the control group had an uneventful postoperative recovery. The assumption of normality and homogeneity of variances was not met; therefore, the Wilcoxon signed-rank test was used to conduct a statistical comparison between the average pH/hour of the control and CAL groups to determine the time of CAL diagnosis using NERv's Inline Device. A significant difference between in pH was seen at POH 5 indicating that NERv's Ihnline Device detected the leakage 2 hours after anastomotic leak induction.



	POH 1	POH 2	POH 3	POH 4	POH 5	POH 6	POH 7
Control	7.55	7.74	7.99	8.15	8.22	8.37	8.34
CAL	7.48	7.73	7.77	7.95	7.61	7.68	7.68
p	0.2517	0.5301	0.1838	0.3242	0.02857	0.02857	0.02857

Descriptive statistics were used to characterize electrical conductivity (EC) for each group. The mean EC for the CAL group (14.3±0.77mS/cm) was higher than that of the control group (13.6±0.38mS/cm) indicating a higher total concentration of ions in the CAL group. Median EC for the control group was skewed to the right, with minimal spread. The EC for CAL group while normally distributed, was highly variable. Results from the two-sided statistical analysis revealed that the EC of the CAL group was significantly different than that of the control group (p-value = 3.3e-5 ($p<0.05$).

Conclusion

Data collected through this study provides robust evidence that continuous pH and electrical conductivity measured using NERv's Inline Device can be used for the early diagnosis of CAL.

References

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