An Impedance and Temperature-Based System for Accurate Feeding Tube Placement in Neonates

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Background

Feeding tube (FT) placement is vital for neonates unable to feed orally. Ensuring correct tube position and identifying misplacements are key to preventing complications. While methods such as auscultation or x-rays are common, more accurate techniques with reduced risks are a vital unmet need for these vulnerable infants.

Objective

To evaluate accuracy of a novel impedance and temperature-based platform designed to predict safe intragastric placement of feeding tubes in neonates.

Methods

Patient characteristics Our IRB-approved study enrolled 16 preterm neonates who required gastric feeds.

Device Design: The distal ends of the 5Fr or 8Fr FTs were integrated with 6-8 electrodes and 3 temperature sensors (**Fig 1**).

Data Collection & Analysis: During each placement attempt, the tube was inserted partially to a 'safety check' depth and paused for the temperature sensors to detect any fluctuations due to air flow. Temperature fluctuations, if detected, indicate that the tube is in the airway, not the esophagus. Notably, the clinical team was blinded to the results of the safety check and used standard methods for full insertion. Feeding tube placement was eventually verified by auscultation, depth verification or X-ray per clinical team's preference.

Results

We made 20 feeding tube (FT) insertions using 5Fr (n=17) and 8Fr (n=3) tubes. Four insertions resulted in tubes curling in the pharynx (n=4) at the Safety Check depth, and one curled in the esophagus at final depth (n=1).

The temperature and impedance-based algorithm could accurately verify a) initial insertion into the esophagus (no respiration temperature cycling detected) vs airway at the Safety Check depth, followed by b) esophageal positioning (2000Ω < impedance < 20000Ω) vs intragastric positioning (impedance < 2000Ω) at final depth, as verified by abdominal X-rays.

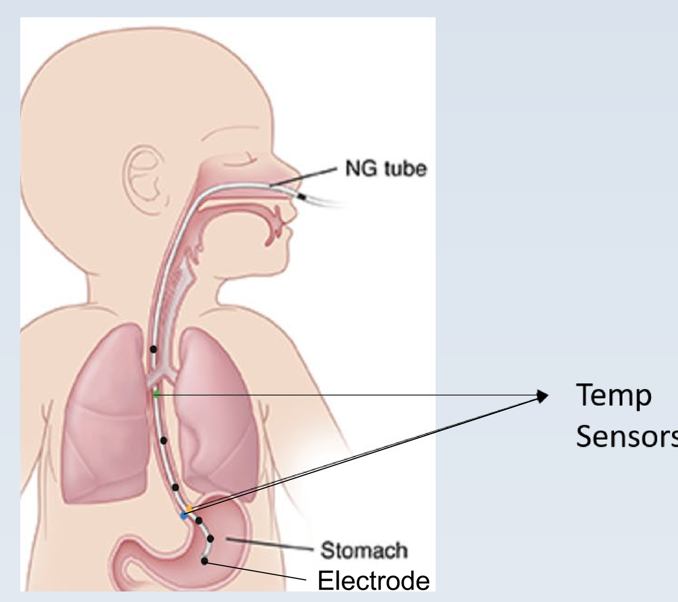


Figure 1 Schematic representation of the impedance and temperature-based FT

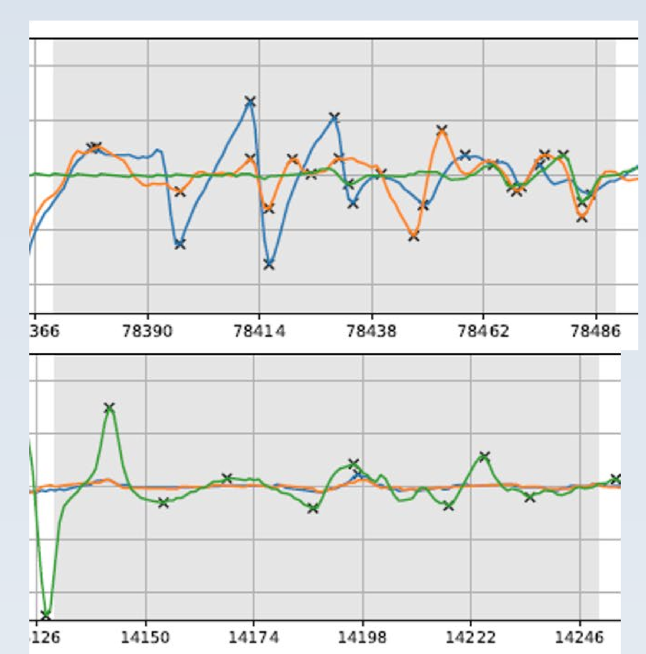


Figure 2a The temperature sensors detected air flow, signifying incorrect placement. The feeding tube was curled back into the pharynx.

Figure 2b The distally located blue and orange temperature sensors do not detect air flow, signifying correct placement in the esophagus. The green sensor is the most proximal temperature sensor and can detect air flow currents (e.g. CPAP/respiration).

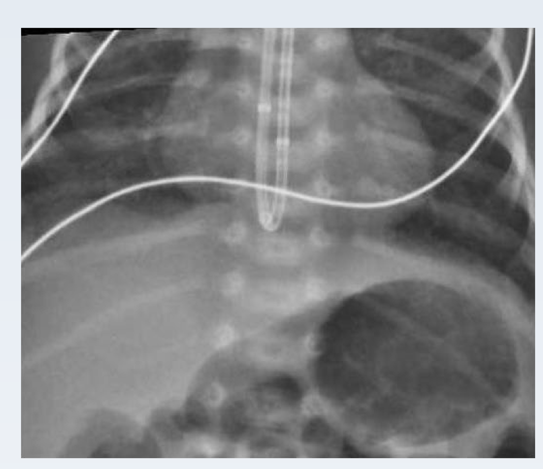


Fig 3a

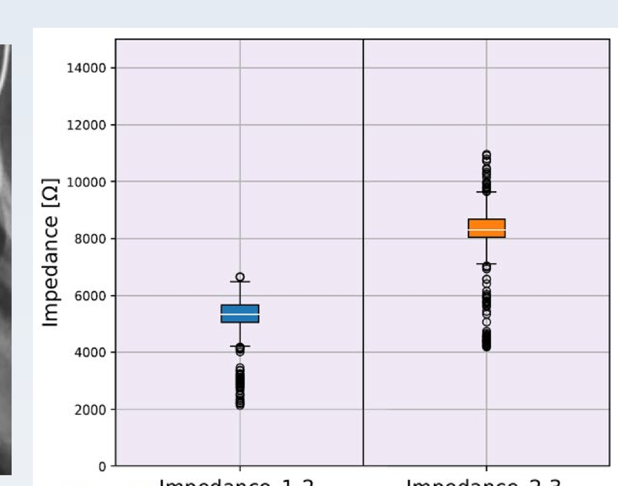


Fig 3b

A curled up esophageal tube (Fig. **3a**) is associated with an impedance between electrode pairs of > 2000 Ω (Fig. **3b**).

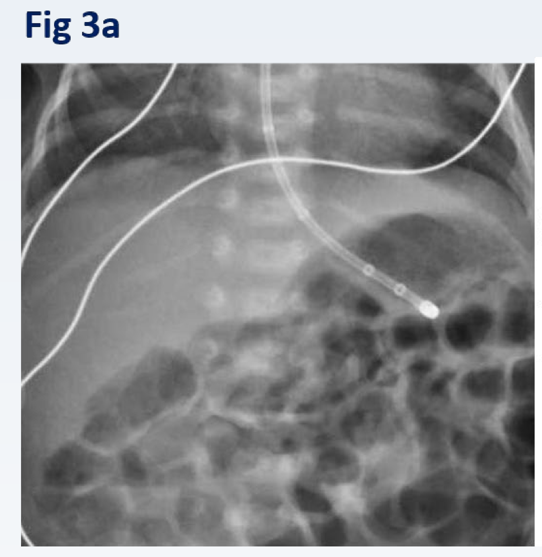


Fig 3c

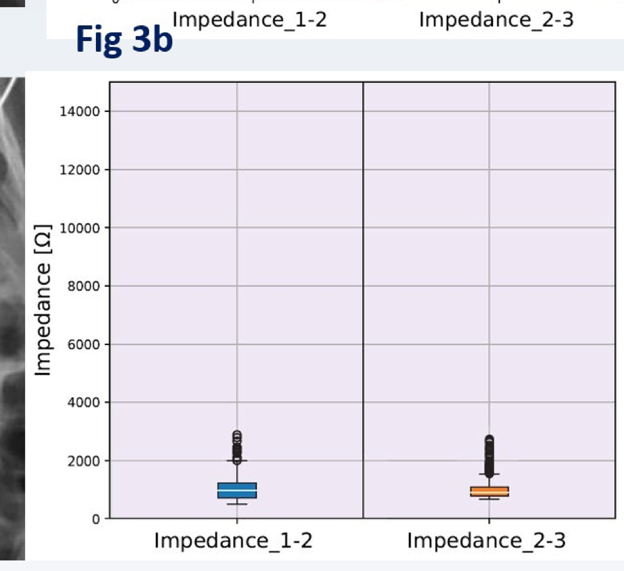
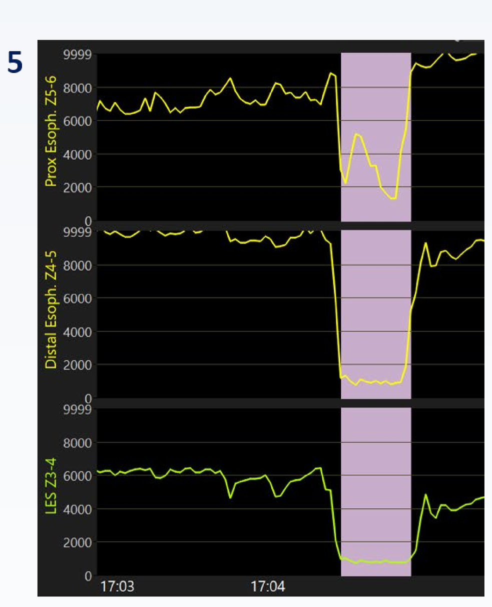


Fig 3d

In contrast, successful gastric placement of the feeding tube (Fig. **3c**) is associated with impedance between electrode pairs of < 2000 Ω (Fig. **3d**).



4a: Percent time spent having reflux episodes during a feeding cycle

4b: Temporal trend of impedance demonstrating a rise from its baseline with feeding and decline towards the baseline with gastric emptying over a 150 minute feeding cycle.

Fig 5. A reflux event identified in real-time signified by an antegrade drop in impedance (pink segment) resulting from milk receding into the esophagus.

Conclusion

1. This novel study shows that an impedance and temperature-based method can accurately guide feeding tube placement, and monitor gastric impedance.
2. The FDA has awarded the device a Breakthrough Designation based on these findings
3. The system has the ability the ability to (a) detect gastroesophageal reflux in real-time and (b) visualize gastric emptying patterns, thereby offering the possibility of developing personalized feeding regimens.