Validation of the RightLevelpH™ Detector for Monitoring Gastric pH

Running Title: Gastric pH Monitoring

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ABSTRACT

Background: The RightLevelpH™ indicator is a new device designed to measure pH of gastric aspirate obtained via nasogastric tube while minimizing exposure of the operator.

Study Objectives: In vivo and in vitro validation of the RightLevelpH™ indicator.

Methods: Patients (23) undergoing general anesthesia had placement of a nasogastric tube and gastric pH electrode catheter following endotracheal intubation. Direct intragastric pH was recorded simultaneously with gastric aspirate pH using the RightSpotpH™ indicator as well as an external pH electrode. Measurements were made every 30 minutes until removal of the nasogastric tube as indicated clinically. In vitro validation of the RightLevelpH™ indicator was performed using standard buffer solutions.

Results: The pH of clear buffer solutions was linearly related to pH determined by the RightLevelpH™ indicator (R²=0.99, P≤0.0001). The pH of gastric aspirate determined by external pH electrode was linearly related to the gastric aspirate pH determined by the RightLevelpH™ indicator (R²=0.92, P≤0.0001). Intragastric pH determined by catheter electrode was also linearly related but more loosely correlated to gastric aspirate pH determined by external pH electrode (R²=0.52, P≤0.0001) and by the RightLevelpH™ indicator (R²=0.56, P≤0.0001).
Conclusions: The RightLevelpH™ indicator provides accurate determination of gastric aspirate pH in patients.
INTRODUCTION

Monitoring gastric pH may be useful in preventing stress ulceration and gastrointestinal bleeding, especially in intensive care unit patients. Determination of gastric pH, in this setting, may be done using an intragastric catheter pH electrode or measuring gastric aspirate pH, either by electrode or indicator paper. The RightLevelpH™ detector is a new device that attaches to a standard nasogastric tube for measurement of aspirate pH using indicator paper technology while minimizing potential exposure to body fluids (Figure 1). The present study compares pH measurements obtained by intragastric catheter pH electrode to that of gastric aspirate determined by external pH electrode and the RightLevelpH™ detector in patients.

METHODS

The Florida Hospital Tampa Institutional Review Board approved this study that was conducted from January to July of 2012. All patients were 21 years of age or older and had a planned elective procedure requiring general anesthesia with endotracheal intubation and placement of a nasogastric tube. A standard nasogastric tube was secured by suture to a pH electrode catheter (Versaflex™) and introduced orally by the attending anesthesiologist following endotracheal intubation. Prior to introduction, the pH catheter was calibrated using buffer solutions per the manufacturers direction.
Auscultation was also routinely done following tube placement as standard practice.

Following placement, gastric aspirate was withdrawn using a standard syringe attached to the RightLevelpH™ indicator and a simultaneous reading of direct intragastric pH was taken from the electrode catheter. If enough gastric aspirate was present, pH was also measured with a laboratory pH electrode. Patients were excluded who had grossly bloody nasogastric aspirate. All operators were previously tested for color blindness (Ishihara). Measurements were then repeated at 30 minute intervals until the nasogastric tube was removed.

Results were analyzed comparing direct intragastric pH versus the RightLevelpH™ indicator reading and external laboratory pH electrode measurement using linear regression. Similarly, the RightLevelpH™ indicator reading was compared to the determination of aspirate pH by the external laboratory pH electrode. An in vitro validation study was done using standard clear buffer solutions of pH 2-7. A total of 46 measurements were made in blinded fashion using the RightLevelpH™ indicator and data were analyzed in the same manner as for the in vivo comparisons.

Values for pH from electrodes were recorded to 0.01 unit while values for pH by RightLevelpH™ indicator were recorded as 1, 2, 3, 4, 5 or ≥6.

RESULTS
A total of 23 patients were enrolled in the study. Data were collected from 17, the others having no gastric aspirate (4) or grossly bloody aspirate (2). No complications occurred during the study.

Results for the in vitro validation revealed a significant linear relationship between RightLevelpH™ indicator determinations (N=83) and actual pH of clear buffer solutions (P≤0.0001) where RightLevelpH™= 1.01(Actual pH)-0.02 with R²=0.99.

The relationship between the pH of 120 gastric aspirate samples determined by external pH electrode and the RightLevelpH™ indicator is illustrated in figure 2. A highly significant linear relationship is seen between the two methods validating pH determination of gastric aspirate by the RightLevelpH™ indicator when compared to a standard laboratory pH electrode.

Figure 3 illustrates the relationship between intragastric pH determined by catheter electrode with gastric aspirate pH determined by the RightLevelpH™ indicator. Figure 4 illustrates the relationship between intragastric pH determined by catheter electrode with gastric aspirate pH determined by the external pH electrode. Although significant linear relationships are observed between both external methods for gastric aspirate pH determination, there is significant variability between direct intragastric pH determined by catheter electrode and both external determination methods.

DISCUSSION
Determination of gastric aspirate pH has been of interest primarily in the context of stress ulcer prophylaxis (1, 2) and nasogastric tube placement (3-5). Methods for determining the pH of gastric aspirate have most commonly utilized either indicator paper or a pH electrode while direct intragastric pH measurement has utilized catheter or capsule based measurement technology (6-21).

Use of pH indicator paper or a pH electrode at the bedside requires aspiration of gastric contents and subsequent handling of the sample to directly touch the indicator paper or pH electrode. After measurement, disposal of the sample and associated hardware as well as cleaning and storage of the pH electrode and meter are required.

The RightLevel™ was designed to offer a quick, inexpensive solution for determination of gastric pH obviating the need for complicated electrode based pH measurement equipment concerns and avoiding contact with gastric aspirate.

The current study validates the RightLevel™ system in vitro using buffers and for determination of gastric aspirate pH by comparison to simultaneous pH electrode measurement on the same samples. In addition, the RightLevel™ system correlates with direct measurement of intragastric pH by catheter electrode similarly to external electrode measurement of gastric aspirate.
The RightLevelpH™ indicator offers accurate determination of gastric aspirate pH equivalent to that of pH electrode determinations in patients.
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FIGURE LEGENDS

Figure 1.
The RightLevelpH™ indicator connects to a standard nasogastric tube allowing aspiration of fluid into a chamber containing pH-indicating paper.

Figure 2.
The relationship between gastric aspirate pH determinations performed using a laboratory pH electrode and the RightLevelpH™ indicator. Dotted lines indicate the 95% confidence intervals for the linear regression. Best fit line: (pH by external pH electrode)=1.29 (pH by RightLevelpH™ indicator)-(0.61).

Figure 3.
The relationship between intragastric pH determined by catheter tip electrode and gastric aspirate pH determined using the RightLevelpH™ indicator. Dotted lines indicate 95% confidence intervals for the linear regression. Best fit line: (pH by RightLevelpH™ indicator)=0.67 (pH by catheter tip electrode)+(1.04).

Figure 4.
The relationship between intragastric pH determined by catheter tip electrode and gastric aspirate pH determined using a laboratory pH electrode. Dotted lines indicate 95% confidence intervals for the linear regression. Best fit line: (pH by external electrode)=0.87 (pH by catheter tip electrode)+(0.64).