

VALIDATION OF THE RIGHTLEVELPH DETECTOR FOR MONITORING GASTRIC pH

By Charles R. Lambert, MD, PhD, MBA, David Varlotta, DO, Marjorie Posey, BSN, Jadie L. Heberlein, BSN, MPH, and Janice M. Shirley, MPH, MBA

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

Objective To validate the RightLevelpH indicator in vivo and in vitro.

Methods With general anesthesia, 20 patients had placement of a nasogastric tube and a gastric pH electrode catheter after endotracheal intubation. Direct intragastric pH was recorded simultaneously with gastric aspirate pH by using the RightLevelpH indicator and by using 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 by using standard buffer solutions.

Results The pH of clear buffer solutions was linearly related to pH determined by the RightLevelpH indicator ($R^2=0.99$; $P<.001$). The pH of gastric aspirate determined with an external pH electrode was linearly related to the gastric aspirate pH determined by using the RightLevelpH indicator ($R^2=0.92$; $P<.001$). Intragastric pH determined with the catheter electrode was also linearly related but more loosely correlated with gastric aspirate pH determined by using an external pH electrode ($R^2=0.52$; $P<.001$) and by the RightLevelpH indicator ($R^2=0.55$; $P<.001$).

Conclusions The RightLevelpH indicator provides accurate measurements of the pH of gastric aspirate in patients. (*American Journal of Critical Care*. 2015;24:211-215)

Monitoring gastric pH may be useful in preventing stress ulcers and gastrointestinal bleeding, especially in critically ill patients.^{1,2} In an intensive care unit, gastric pH can be determined by using either an electrode or indicator paper. The RightLevelpH detector is a new device with indicator paper technology that attaches to the proximal end of a standard nasogastric tube for measuring aspirate pH while minimizing potential exposure to body fluids (Figures 1 and 2). This device provides a closed system for aspiration of fluid (1 mL) that flows over the indicator paper visualized in the window of the detector. The color change of the indicator paper is compared with a color scale next to the window on the device (Figure 1). The device is discarded after use.

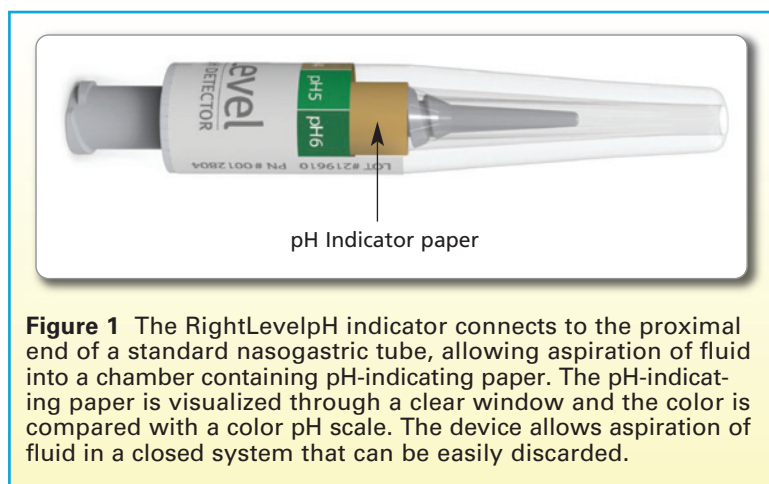


Figure 1 The RightLevelpH indicator connects to the proximal end of a standard nasogastric tube, allowing aspiration of fluid into a chamber containing pH-indicating paper. The pH-indicating paper is visualized through a clear window and the color is compared with a color pH scale. The device allows aspiration of fluid in a closed system that can be easily discarded.

In this study, we compared pH measurements obtained by using an intragastric catheter pH electrode with pH measurements of gastric aspirate determined by using an external pH electrode and the RightLevelpH detector in patients. This study is the first in vivo human validation study for this device.

Methods

The study was approved by the institutional review board at Florida Hospital Tampa. From January to July 2012, patients were included in the

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study if they were 21 years or older, were scheduled for a planned elective procedure requiring general anesthesia with endotracheal intubation and placement of a nasogastric tube, and were able to give informed consent. The only exclusion criterion was the presence of grossly bloody aspirate.

A standard nasogastric tube was secured by suture to a pH electrode catheter (Versaflex, Given Imaging) and introduced orally by the attending anesthesiologist after endotracheal intubation. Before placement, the pH catheter was calibrated by using buffer solutions per the manufacturer's direction. Auscultation was also routinely done after tube placement.

When a set of measurements were obtained, pH was determined first by using the intragastric pH electrode catheter and recorded and then by aspirating gastric contents via the nasogastric tube through the RightLevelpH indicator into a syringe. The RightLevelpH indicator measurement was recorded, and then gastric aspirate remaining in the syringe was placed into a container for pH determination via the external electrode. This electrode (Model 1112000, Thermo Scientific Environmental Instruments) was calibrated by using buffer solution before each measurement.

All operators were previously tested for color blindness (Ishihara color vision test). Measurements of pH were then repeated at 30-minute intervals until the nasogastric tube was removed.

Linear regression was used to compare direct intragastric pH measurements with pH values obtained by using the RightLevelpH indicator and the external laboratory pH electrode. Similarly, the RightLevelpH indicator value was compared with the aspirate pH measurement obtained by using the external laboratory pH electrode. An in vitro validation study was done by using standard clear buffer solutions of pH 2 to pH 7. A total of 83

measurements of buffer solution pH were made in blinded fashion with the RightLevelpH indicator, and data were analyzed in the same manner as data for the in vivo comparisons.

Values for pH measured by using electrodes were recorded to 0.01 unit, whereas values for pH measured by using the RightLevelpH indicator were recorded as 1, 2, 3, 4, 5, or 6 or more.

Results

A total of 28 patients consented to participate in the study. The patients were sequential and were approached for participation during the preoperative visit. Patients were not given proton pump inhibitors or antacids and had nothing by mouth after midnight before their procedure as standard clinical practice. Data were collected from 20 patients; the other patients were excluded because of no aspirate, bloody aspirate, or the surgeon's request. No complications occurred during the study.

As noted earlier, measurements were made until use of the nasogastric tube was discontinued as indicated clinically. In total, 154 measurement periods were recorded in 20 patients. The number of measurement periods for a given patient ranged from 2 to 10 (mean, 14; SE, 7). Thus, the duration of use of a nasogastric tube in these elective surgical patients ranged from 1 hour to 20 hours. Intra-gastric electrode measurements were recorded for all 154 periods, RightLevelpH measurements were made for 130 periods, and external pH measurements were made for 120 periods. These differences were due to the volume of available gastric aspirate.

Results for the in vitro validation revealed a significant linear relationship between RightLevelpH indicator determinations ($n=83$) and actual pH of clear buffer solutions ($P=.001$), where the best-fit line was $\text{RightLevelpH} = 1.01(\text{actual pH}) - 0.02$ with $R^2=0.99$.

The relationship between the pH of 120 gastric aspirate samples determined by using an external pH electrode and by using the RightLevelpH indicator is illustrated in Figure 3. The gastric aspirate was placed into a small sampling beaker into which the pH electrode was placed after calibration of the electrode according to standard laboratory technique. A highly significant linear relationship is apparent between the 2 methods, validating pH determination of gastric aspirate by the RightLevelpH indicator compared with determination via a standard laboratory pH electrode.

Figure 4 shows the relationship between intra-gastric pH determined by using a catheter electrode and the pH of gastric aspirate determined with the



Figure 2 Use of the RightLevelpH indicator as described in the text.

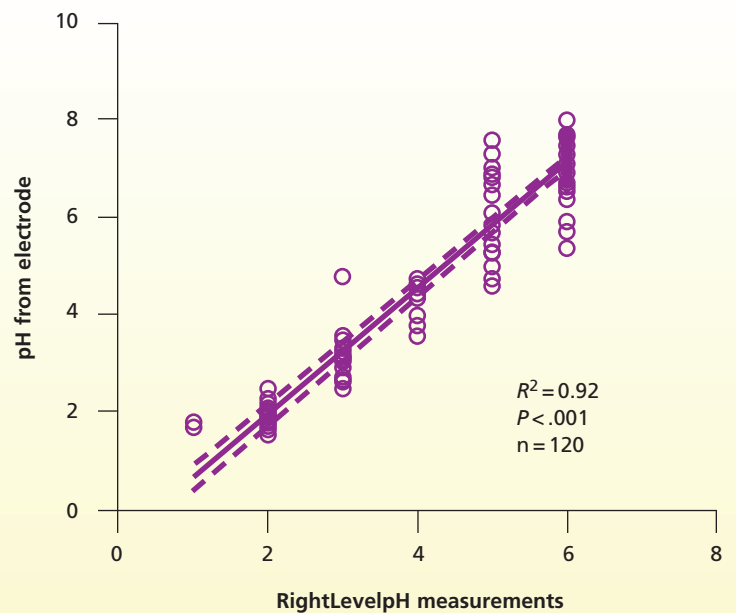


Figure 3 Relationship between measurements of pH of gastric aspirate obtained with a laboratory pH electrode and with the RightLevelpH indicator. Dotted lines indicate the 95% CIs for the linear regression. Best-fit line: $(\text{pH by external pH electrode}) = 1.29(\text{pH by RightLevelpH indicator}) - 0.61$.

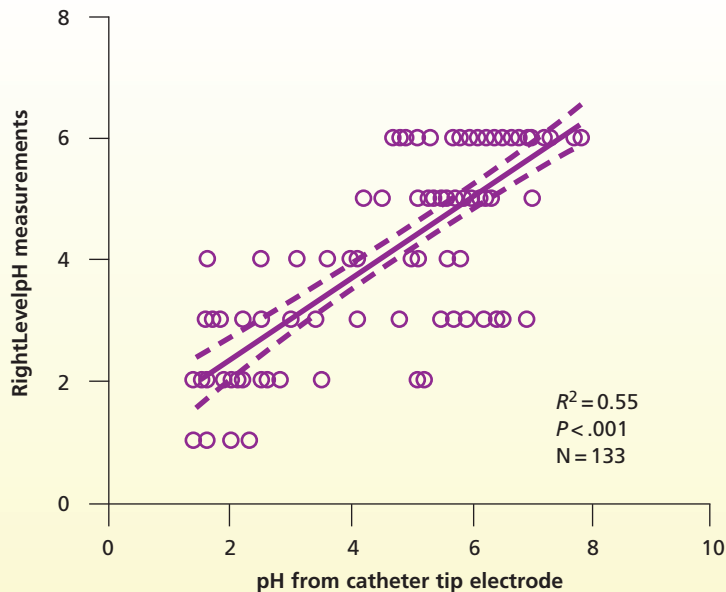


Figure 4 Relationship between measurements of intragastric pH obtained with a catheter tip electrode and measurements of gastric aspirate pH obtained with the RightLevelpH indicator. Dotted lines indicate 95% CIs for the linear regression. Best-fit line: (pH by RightLevelpH indicator) = 0.67 (pH by catheter tip electrode) + 1.04.

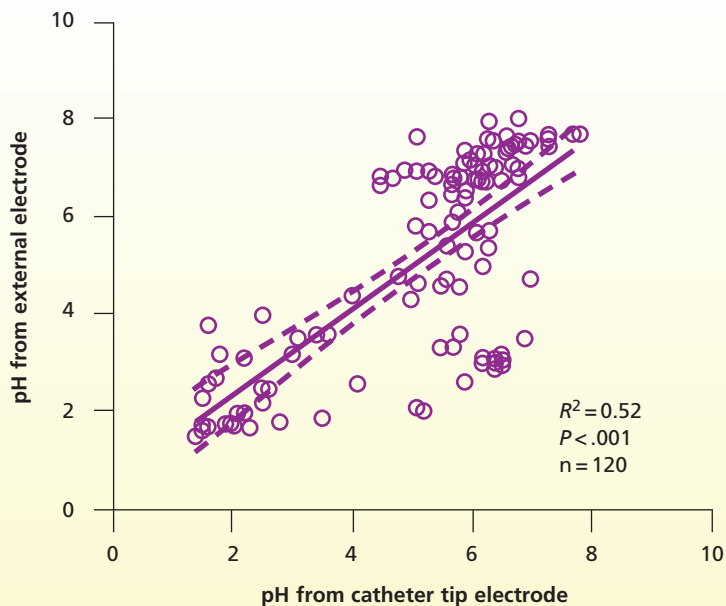


Figure 5 Relationship between measurements of intragastric pH obtained with a catheter tip electrode and measurements of gastric aspirate pH obtained with a laboratory pH electrode. Dotted lines indicate 95% CIs for the linear regression. Best-fit line: (pH by external electrode) = 0.87 (pH by catheter tip electrode) + 0.64.

RightLevelpH indicator. Figure 5 depicts the relationship between intragastric pH determined by using a catheter electrode and gastric aspirate pH determined

by using an external pH electrode. Although we detected significant linear relationships between both external methods for determining the pH of gastric aspirate, we found significant variability between measurements of direct intragastric pH determined by using a catheter electrode and measurements obtained with both external determination methods.

Discussion

Determining the pH of gastric aspirate has been of interest primarily in the context of preventing stress ulcers^{1,2} and placing nasogastric tubes.³⁻⁵ Methods for determining the pH of gastric aspirate have most commonly entailed use of either indicator paper or a pH electrode. In direct measurement of intragastric pH, a catheter or capsule-based method is used.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 RightLevelpH was designed to offer a quick, inexpensive solution for determining pH without the use of complicated electrode-based pH equipment and for avoiding contact with gastric aspirate.

We validated the RightLevelpH system in vitro by using buffers and by comparing measurements of gastric aspirate pH with simultaneous pH measurements obtained with a pH electrode on the same samples. In addition, measurements obtained with the RightLevelpH system correlated with direct measurements of intragastric pH via a catheter electrode.

The correlation between intragastric pH determined by using a catheter electrode and values of gastric aspirate pH measured externally by using either an electrode or the RightLevelpH indicator was less than the correlation between pH measurements obtained by using an external pH electrode and measurements obtained via the RightLevelpH indicator. This finding is not surprising when the observations of others^{6,17,18,22-25} are considered and may be due to regional differences in gastric pH and contact of the electrode catheter with the mucosa.

The RightLevelpH indicator offers accurate determination of gastric aspirate pH equivalent to that of pH electrode determinations in patients.

FINANCIAL DISCLOSURES

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