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and higher birth weights associated with physical exam-indicated cerclage, although only one randomized trial was available for the analysis. "A concern with physical examination-indicated cerclage is that it may prolong pregnancy long enough only to result in an extremely preterm delivery," note Robert Ehsanipoor, MD, from the Department of Gynecology and Obstetrics at Johns Hopkins University in Baltimore, Maryland, and colleagues. "However, we found that expectant management was associated with a more than fourfold increased risk of delivery between 24 and 28 weeks of gestation." They continue, "The current literature suggests that physical examination-indicated cerclage is associated with markedly improved outcomes." Still, an important caveat of their analysis includes the limited quality and small size of the included studies. The researchers searched six databases for studies published between 1966 and 2014 that compared cerclage with expectant management for treating cervical insufficiency. Cervical insufficiency, defined as painless second semester cervical dilation, occurs in less than 1% of pregnancies, and few data exist for assessing the benefit of cerclage to prevent pregnancy loss.

Maternal PCOS Linked to Problems

Maternal polycystic ovary syndrome (PCOS) may have long-lasting adverse health consequences for offspring, according to a study published online May 11 and in the June issue of *Obstetrics & Gynecology*. Offspring of affected mothers had higher odds of congenital anomalies than peers of unaffected mothers and were 14% to 69% more likely to be hospitalized for various health conditions, with the elevated risk persisting into at least young adulthood. "In view of our findings and the purported association of periconception, metabolic derangements with

poor implantation and placentation[,] strategies to improve periconception health in women with PCOS may be expected to improve reproductive outcomes," write Dorota A. Doherty, PhD, from the School of Women's and Infants' Health, University of Western Australia in Subiaco, and colleagues. Both normal-weight status and metformin therapy have been linked to better pregnancy outcomes in this population, they note. "Hence, preconception identification of women with PCOS may enable early intervention to improve long-term outcomes, although it is not clear if all women with PCOS have this increased risk for adverse outcomes or whether there are certain features of PCOS that are associated with particular outcomes for the mother and her offspring," they maintain. The study is important as it is apparently the first to report a link between maternal PCOS and health outcomes of offspring in early life, according to Kathleen Hoeger, MD, a professor of obstetrics and gynecology and director of the Reproductive Endocrine Division, University of Rochester Medical Center, New York. In addition, PCOS is common among women of reproductive age but is often underappreciated in general pregnancy care.

Newborns and CF

Eleven percent of infants who had inconclusive results for cystic fibrosis (CF) as newborns went on to develop the disease by age 3 years, underscoring the need for additional tests by skilled clinicians, including monitoring of sweat chloride and searching for disease-causing mutations, according to a prospective longitudinal study. The study, by Chee Y. Ooi, MBBS, PhD, from the Discipline of Pediatrics, School of Women's and Children's Health, Faculty of Medicine, University of New South Wales, Sydney, Australia, and colleagues, is one of two

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Validation Study of the RightSpot Infant pH Indicator for Verification of Feeding Tube Placement in the Neonatal Intensive Care Unit

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Abstract

Background: Improper feeding tube placement in infants is a cause of increased cost and morbidity.¹ The RightSpot infant pH indicator is a device that measures the pH of aspirates from feeding tubes to help determine proper placement. Previous studies have shown that a low pH reading would indicate proper placement of the NG tube in the stomach.² A study was necessary to ensure the accuracy and validity of the RightSpot pH indicator.

Objectives: The aim of the study was to validate the accuracy of the RightSpot indicator's pH measurement of gastric aspirates by comparing the results with a standard pH monitor for neonates at different ages and gestations.

Methods: This prospective observational study enrolled 31 subjects from September 2014 to January 2015. Up to eight samples were obtained per subject totaling 240 samples. Infants with congenital anomalies were excluded. Infants who were not feeding, receiving an acidified liquid human milk fortification or medications known to alter the pH of gastric contents were also excluded. Gastric samples were aspirated through the Right Spot indicator and applied to the pH meter prior to the infant's feeding. Readings from the two devices were recorded and compared. Data was collected on gestational age, day of life, length of feeds, residual amount and the type of feeding. Descriptive statistics are provided.

Results: The RightSpot indicator was accurate 100% of the time within a pH of ± 0.5 on 236 samples when compared to the measurements of the same sample taken with the Scientific Instruments pH meter I-12. A pH below 5.9 was noted in all of the 240 samples. In 189 samples a pH below 4.5 was noted. The pH ranged from 0.9 to 5.9 without correlation to age, corrected gestational age, weight, residuals and the time of the last feeding.

Background

Improper feeding tube placement in infants is a cause of increased cost and morbidity in the Neonatal Intensive Care Unit (NICU).¹ Ellett and Beckstrand's study report the rates of feeding tube misplacement in children range from 21.8% to 43.5%.² The improper placement of a feeding tube in the respiratory

tract can be lethal. In 2005, the Joint Commission in the United States classified the placement of a feeding tube in the trachea or bronchus as a Sentinel Event.³ Although radiologic methods are considered the gold standard for determining feeding tube placement, the use of radiologic methods can cause harm when used repeatedly in the neonatal population.¹ An assessment device that could decrease the necessity of radiologic methods was needed to help verify correct gastric placement of feeding tubes. Routinely, NICUs require that nasogastric (NG) tube placement is confirmed using both radiologic and non-radiological methods including auscultation, aspiration, and tube measurement. Unfortunately, clinicians remain uncertain about the reliability of bedside methods.⁴

At the study center, Banner - University Medical Center Phoenix, NICU guidelines require NG tube placement is confirmed after initial tube insertion, before every feed, before medication administration and any time tube placement is questioned. Methods of confirming feeding tube placement include auscultation, aspiration, and measurement of the depth of the feeding tube. Auscultation involves instilling a small amount of air in the feeding tube while listening through a stethoscope placed over the stomach. If a "whoosh" is heard, the feeding tube is considered to be placed correctly. Unfortunately this technique is not always reliable as an infant's thin abdominal wall allows sounds to be transmitted to the stomach regardless of whether the feeding tube is placed in the respiratory tract, lung, esophagus, stomach, or intestine.^{5,6} A second method of placement confirmation involves the aspiration of a small amount of gastric contents. Misinterpretation can occur as the pulmonary aspirates can be similar to gastric aspirates in coloration. Although The National Patient Safety Agency excluded neonates from their Reducing the Harm Caused by Misplaced Nasogastric Feeding Tube Guidelines, they recommend that observation of the appearance of the aspirate should not be used in infants to verify correct placement of feeding tubes.⁷ A third method of tube placement confirmation is the measurement of the depth of the feeding tube. This is accomplished by measuring the distance from the ear to nose to xiphoid process and making note of where the feeding tube lies at the nostril.⁸ This process of confirmatory assessment occurs multiple times throughout the day.

Right BioMetrics, has developed the RightSpot infant pH indicator, a device that rapidly verifies gastric pH as the caregiver aspirates contents from a nasogastric (NG) or orogastric (OG) tube. The device has the ability to report pH measurements

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within a 0.5 pH unit with a range of 4.5-7.0. A corresponding color change occurs within the device allowing the caregiver to confirm initial tube placement in the stomach as well as subsequent necessary confirmations. A study was needed to ensure the accuracy and validity of the RightSpot pH indicator in the clinical setting.

Primary Objective

To validate the accuracy of the RightSpot indicator's pH measurement of gastric aspirates by comparing the results with a standard pH monitor for neonates at different ages and gestation.

Secondary Objective

To describe pH values for neonates.

Methods

Eligible patients were identified based on the study's inclusion/exclusion criteria. The objectives and requirements of the study were explained to the parents or legally authorized representatives of the infants. Ample time was given to review and discuss the informed consent. The criteria for enrollment were as follows:

1. Inclusion Criteria
 - Infants in the Newborn Intensive Care Unit with an NG tube in place
2. Exclusion Criteria
 - Infants with congenital or genetic abnormalities
 - Infants with gastroschisis
 - Infants with upper airway abnormalities: Choanal atresia, cleft palate, or tracheal-esophageal fistula
 - Infants receiving any supplement or medication known to alter the pH of gastric contents
 - Infants receiving Enfamil liquid human milk fortification
 - Infants who were NPO status

Prior to the NG tube feedings, gastric aspiration was performed to verify feeding tube placement. The research nurse would place the RightSpot pH indicator device in the opening of the NG tube and aspirate approximately 1 ml of gastric contents. Up to 8 samples were obtained at different scheduled feedings for each subject enrolled. The pH value displayed by the RightSpot pH indicator was visualized and recorded. A sample of the same aspirate was then applied to the clinically approved pH monitor and these results were recorded. Readings from the Right Spot infant pH indicators were compared to the readings from the Scientific Instruments pH meter I-120. The pH meter was calibrated prior to each sample collection.

Permission for usage of the device was received from the FDA as a waiver under the Clinical Laboratory Improvement Amendment (CLIA) of 1988. The study received Institutional Review Board oversight from Banner Health.

Statistics

The data was analyzed to determine the agreement and accuracy of two modes of gastric pH measurement by comparing the readings from a pH indicator to a standard clinically approved monitor. Agreement by intraclass correlation co-efficient (ICC) was obtained to compare the pH readings from the RightSpot indicator and the pH readings from the clinically approved pH monitor. The ICC estimates are presented with 95% confidence intervals (CI). The bias and

precision of measurement by the test indicator in comparison to the clinically approved monitor was assessed by the Bland-Altman method. Accuracy was determined by estimating the root mean square of differences.

The data, clustered on the subject, were evaluated per subject to identify variability or demonstrate homogeneity. In the presence of homogeneity, only the first measurement was used. In absence of homogeneity, the data was analyzed with data clustered at the subject level.

Results

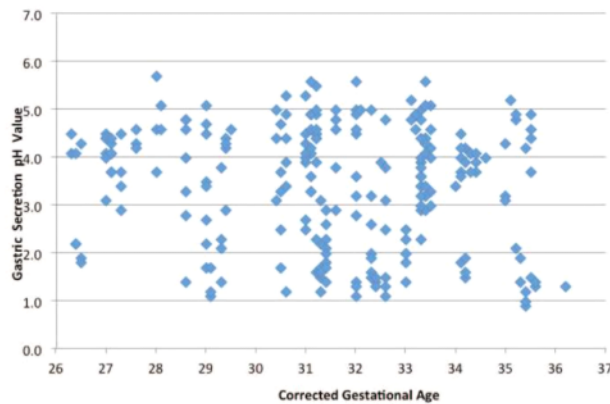
In this prospective observational study 31 subjects were enrolled from September 2014 to January 2015. A total of 240 samples were obtained with 3-8 samples per subject. Mean values for data collection are present in Table 1. The infant's weights were between 705 and 2260 grams with an average weight of 1410 grams at the time of sample collection. The gestational age of the study subjects was between 24 6/7 weeks gestation and 34 0/7 weeks gestation. The adjusted gestational age at the time of sampling was between 26 3/7 days and 36 2/7 days. Samples were obtained from day of life 2 through day of life 67. The average amount time since the last feeding finished prior to obtaining the sample was 2 hours and 15 minutes. Six of the 31 subjects were on liquid protein fortifiers and eight were receiving Neosure powder as a supplement. The mean residual at the time of sample collection was 1.4 ml. NG feeding tubes sizes were 4 and 6 Fr.

The RightSpot Indicator system and the pH meter reported the same gastric pH ± 0.5 on 236 of the samples tested. A pH below 5.9 was noted in all of the 240 samples tested with both methodologies. In 189/240 samples, a pH ≤ 4.5 was noted by both systems. The ICC between the two testing systems was 0.9714 with a variance of 0.1. Proton pump inhibitors were not administered in the study population. The mean gastric pH obtained from this population was 3.4 with a standard deviation of 1.3 and median of 3.5 using the pH meter. The pH ranged from 0.9 to 5.9 without correlation to age, adjusted gestational age, weight, residuals and the time of the last feeding. Table 2 depicts the pH gastric secretions and the lack of correlation to corrected gestational age.

Table 1. Description of Findings.

# Subjects	31
# of Samples	240
Mean weight at time of sample collection (g)	1410
Mean gestational age at birth in completed weeks	29
Mean adjusted gestational age in completed weeks at time of sample	32
Mean day of life at time of sample	18
Mean residual at time of sample collection (ml)	1.4
Mean time from last feeding to sample collection	2h 15min
Mean gastric pH using pH meter	3.4 \pm 1.3
Median gastric pH using pH meter	3.7
Mean gastric pH using RightSpot Indicator	4.6 \pm 0.2
Median gastric pH using RightSpot Indicator	4.5
Correlation and Variance	0.9714 and 0.108

Table 2. Adjusted gestational age at time of sample collection in conjunction with gastric secretion pH value.



Discussion

Acidification of the infant's stomach does not appear to be related to age, gestation, corrected gestation, residuals, weight or timing of the last feeding. The RightSpot pH indicator system is a reliable method of determining gastric pH from an indwelling feeding tube and may be used as a reliable component of the process to confirm placement of NG feeding tubes. This device is non-invasive, disposable, non-radiographic and allows for accurate confirmation of feeding tube placement by nursing. The utilization of pH to confirm feeding tube placement can decrease the need for radiologic methods and the use of ancillary hospital professionals. The RightSpot pH indicator may ultimately decrease costs and the delay of infant feeding. The RightSpot device may increase patient safety by preventing prevent mal-positioned feeding tubes and aspiration events.

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