## Prognostic Values of Multichannel Intraluminal Impedance and pH Monitoring in Newborns with Symptoms of Gastroesophageal Reflux Disease

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**Objective** To evaluate the relationship between multichannel intraluminal impedance and pH monitoring (MII/pH) values in newborns with symptoms of gastroesophageal reflux disease (GERD) and clinical history in their first 3 years of life.

**Study design** Sixty-four newborns with GERD symptoms who underwent MII/pH in the first weeks of life were enrolled into a clinical follow-up program. Follow-up visits were programmed at 1, 3, 6, 9, 12, 18, 24, and 36 months. Patients were divided into 3 groups according to duration of symptoms: short (1-3 months), medium (4-9 months), and long (>9 months), and MII/pH values in these groups were compared.

**Results** Fifty-three patients completed the 3-year follow-up. The number of patients with GERD symptoms decreased each month. A comparison of MII/pH values of the 3 lifetime symptom groups revealed differences in the impedance bolus exposure index (F = 83; P = .012) and proximal reflux frequency (F = 410; P = .022). These 2 MII variables showed an increasing trend from the short lifetime symptom group to the long lifetime symptom group. Weakly acidic reflux events, but not acidic events, were responsible for these differences.

**Conclusion** MII/pH in newborns has prognostic value regarding the duration of GERD symptoms and provides useful information that clinicians may give parents about the prognosis of symptomatic infants. Impedance bolus exposure index and proximal reflux frequency seem to be the variables with the highest predictive value. Weakly acidic reflux events play an important role in determining the duration of GERD symptoms in newborns. (*J Pediatr 2013;162:770-5*).

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astroesophageal reflux (GER) can be considered physiological in the first months of life. In newborns, a retrograde flow of gastric content in the esophagus can occur 2 or 3 times per hour, often accompanied by regurgitation or vomiting but sometimes clinically silent.<sup>1</sup> GER tends to resolve spontaneously and is typically controlled with conservative management. In approximately 5% of newborns, GER is associated with gastroesophageal reflux disease (GERD), characterized by various signs and symptoms related to the frequency and quality of reflux events.<sup>2</sup> The early diagnosis and treatment of GERD is important in the neonatal intensive care unit (NICU), given that the disease can worsen preterm conditions and increase the duration of hospitalization.<sup>3</sup>

Some authors have hypothesized a clinical correlation between GER and apnea in preterm newborns,<sup>4</sup> chronic respiratory diseases and pneumonia,<sup>5</sup> and feeding and growth problems.<sup>6</sup> This hypothesis has led to the pharmacologic treatment of GERD in NICUs both during hospitalization and at discharge based on clinical diagnosis, even when that diagnosis is not supported by testing. It was recently reported that 25% of extremely low birth weight preterm newborns are discharged on medication for GERD, with wide variability across NICUs.<sup>7</sup> This variability stems from the insufficient scientific information on and lack of guidelines for newborn GERD, and demonstrates the need for further study using new, more precise techniques.

Multichannel intraluminal impedance and pH monitoring (MII/pH) detect reflux events as changes in impedance recorded between pairs of electrodes located along a catheter in the esophageal lumen, and determines their pH by means of a pH-sensitive antimony electrode.<sup>8</sup> MII/pH allows the detection not only of esophageal acid exposure, but also nonacidic or weakly acidic reflux events, which are prevalent in newborns.<sup>9</sup> This technique is better able to recognize reflux events than traditional pH-metry<sup>10</sup> and is particularly suitable for use in newborns.<sup>11</sup> Its application in term and preterm newborns

GER	Gastroesophageal reflux
GERD	Gastroesophageal reflux disease
IBEI	Impedance bolus exposure index
MII/pH	Multichannel intraluminal impedance and pH monitoring
NICU	Neonatal intensive care unit
RI	Reflux index

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The authors declare no conflicts of interest.

0022-3476/\$ - see front matter. Copyright © 2013 Mosby Inc. All rights reserved. http://dx.doi.org/10.1016/j.jpeds.2012.10.009 with GERD symptoms has been shown to be safe and well tolerated.<sup>12</sup> MII/pH allows for the observation of some distinctive features of reflux events in these patients, which may influence the subsequent clinical approach.<sup>13</sup> However, the use of MII/pH in infants in clinical practice is currently limited by a lack of data regarding the relationship between the examined MII/pH variables.

The aim of this study was to investigate the relationship between MII/pH values recorded in a cohort of newborns with GERD symptoms and their clinical outcomes evaluated at 3-year clinical follow-up.

## Methods

Patients with clinical symptoms of GERD, based on criteria laid out by the North American Society for Pediatric Gastroenterology and Nutrition,<sup>2</sup> who were admitted to the neonatal care unit of the Sant Anna-Regina Margherita Children's Hospital between 2004 and 2008 and underwent MII/pH were consecutively enrolled into the study. Included patients were term newborns in the first month of life or preterm newborns with a postmenstrual age of 36-46 weeks at MII/pH who had: (1) a valid MII/pH trace for a minimum of 19 consecutive hours, excluding artifacts; (2) absence of pharmacologic therapy for GERD for at least 1 week before undergoing MII/pH; (3) a diet of breast milk or formula (thickened formulas were excluded); and (4) absence of infection, metabolic, or central nervous system disease.

Written informed consent was obtained from the parents of all patients. The study protocol was approved by the Ethical Committee of the Sant Anna-Regina Margherita Children's Hospital.

The Orenstein questionnaire<sup>14</sup> was used as a guideline in the creation of an anamnestic record for each patient, which included detailed anthropometric data (weight, length, head circumference), symptoms, number and amount of meals, previous treatments and doses administered, and any diagnostic examinations performed. Clinical follow-up visits were scheduled at 1, 3, 6, 9, 12, 18, 24, and 36 months after hospital disharge. Follow-up visits could be more frequent if the symptoms worsened or if requested by parents. At enrollment and during follow-up, patients were examined and measured, and parents completed the structured questionnaire, which included questions on whether their infant was showing symptoms; if not, when the symptoms stopped; and if, so what the symptoms were and the corresponding therapy. A telephone interview was conducted with parents who were unable to bring their infant to a scheduled follow-up. We considered patients who were not present at 2 sequential follow-up visits and those who presented with other chronic diseases during the follow-up period as lost to follow-up.

GERD symptoms were categorized as typical (excessive regurgitations, vomiting, and blenching), atypical (crying, irritability, nocturnal waking, and feeding difficulties), and respiratory problems (apneas/desaturations/bradicardia, paleness, cyanosis, and cough). Patients were assigned to 1 or more of these groups based on symptoms at enrollment. To retrospectively evaluate the relationship between MII/ pH variables and duration of GERD symptoms, at the end of the follow-up period patients were classified into 3 lifetime symptom groups: those who had a clinical condition suggestive of GERD for the first 3 months of life or less (short symptom group), those who had this condition for 4-9 months (medium symptom group), and those who had this condition for more than 9 months (long symptom group).

The z-scores of weight and height for age were calculated with the formula z = x - |X|/|SD|, using the Centers for Disease Control and Prevention growth curves as reference at birth, at enrollment, at the cessation of symptoms, and at the end of follow-up, to evaluate changes in anthropometric measurements independent of age. The characteristics of reflux events at enrollment were assessed by MII/pH. A single-use MII/pH intraesophageal probe with a pH-sensitive antimony electrode and 7 integrated impedance electrodes was placed transnasally, with containment and consolation of the newborn, after a 3-hour fasting period. The probe was tested and calibrated before insertion. On insertion, the probe's distal pHsensitive tip was positioned 1.5 cm above the lower esophageal sphincter. The approximate position of the probe was calculated according to the method of Strobel et al,<sup>15</sup> checked fluoroscopically, and corrected if necessary. The catheter was connected to an exterior impedance device (Sleuth System; Sandhill Scientific, Highlands Ranch, Colorado) for signal processing and recording. Impedance was measured bipolarly between paired electrodes that formed 6 impedance channels. The distance between adjacent electrodes was 1.5 cm. The total segment measured extended from 1.5 cm above the lower esophageal sphincter (channel 1, distal) to the pharynx, with the pH sensor located at channel 1.

During MII/pH recording, the patient was kept supine at a 30° incline, and received breast milk or formula from a feeding bottle every 4 hours. The MII/pH traces were evaluated visually by a single operator to avoid interobserver variability.<sup>16</sup> Segments with signal artifacts or interruptions were discarded. An MII reflux event was defined as a decrease in impedance starting in the most distal channel, extending proximally over 2 or more channels, and followed by an increase in impedance back to baseline values. The duration of a reflux event was defined as the time (in seconds) between its onset at the 50% drop in impedance from baseline relative to nadir and bolus exit at the 50% recovery point from nadir to baseline recorded at the distal channel. An event's proximal extent was defined as the number of channels sequentially involved in the temporary impedance decrease. An event was defined as "proximal" when its proximal extent reached the most proximal MII recording site, as located fluoroscopically in the pharynx. The reflux pH was the nadir esophageal pH recorded during the event. According to these values, the reflux events were classified as acidic (pH < 4), weakly acidic (pH 4-7), or weakly alkaline (pH > 7). A pHmetry reflux event was defined as a temporary drop in the pH signal to <4 for longer than 5 seconds.

MII/pH traces were analyzed by evaluating 7 different measures: (1) MII-reflux frequency (reflux events/hour);

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