

Reliability, Safety and Effectiveness of the Bravo™ Capsule: A Catheter-free pH Monitoring System for Evaluation of Gastroesophageal Reflux Disease in Children

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ABSTRACT

BACKGROUND

Gastroesophageal reflux disease (GERD) is a common problem seen in pediatrics and adolescents. The Bravo™ pH Monitoring System is a capsule that detects and quantifies the severity of reflux disease. This test is also valuable for evaluation of patients with extra-gastrointestinal manifestations of GERD such as asthma, chronic cough, hoarseness, aspiration pneumonia, and pre/post fundoplication surgery. This study evaluates the safety and reliability of this procedure in children.

METHODS

From January 2002 to December 2010, 219 patients (85 males and 134 females), ages 6-18 years underwent upper endoscopy with biopsies and placement of the Bravo™ capsule.

RESULTS

In 201 out of 219 patients, the Bravo™ pH monitoring procedure completed within 48 hours without any complaints. In 3 out of 219 patients, the pH dropped to less than 2 after 30 minutes. This indicated that the capsule moved from the esophagus to the stomach. One other patient deleted all data while playing with the recorder at home. In another patient, there was recorder malfunction. Three patients presented with chest pain, one with chest and back pain and nine patients had a mild sensation of sub-sternal pain for two hours or less. None of the patients needed to retrieve the capsule.

CONCLUSION

Bravo™ capsule pH monitoring of the esophagus is reliable, safe, well tolerated and free from significant complications, and preferred by young adolescents. With the Bravo™ capsule, adolescents can attend school and continue their normal physical activities without interruption.

KEYWORDS

GERD; Esophageal pH; Asthma; Fundoplication; Heartburn; Bravo™ pH Test.

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INTRODUCTION

Gastroesophageal reflux disease (GERD) often has its origin in early infancy. Children and adolescents with GERD usually have a history of vomiting and spitting up as an infant.¹ If GERD is left untreated, it can lead to dysphagia, odynophagia, esophageal stricture, chronic hoarseness, laryngitis or respiratory problems such as coughing or reactive airway disease in children and non-cardiac chest pain or Barrett's esophagus in adults.

Proper evaluation and appropriate therapy may result in better long-term outcomes, such as improved quality of life and reduction in the overall health-care burden. The Gastroesophageal symptoms are often atypical in children. Traditional catheter-based esophageal pH monitoring is uncomfortable and cumbersome; many parents may forego testing for their children, leaving them undiagnosed and consequently untreated or under treated for this disorder.

In some patients otolaryngologic or respiratory symptoms may be the only indication of GERD. Gastric juices have been detected in the middle ear, which this indicates that GERD can cause chronic otitis media with fluid collection.²

Testing with a pH probe can cause nasal and throat irritation in some, impairing the ability to maintain a normal diet. The catheter itself remains visible, causing many patients to alter their exercise and activity routines during the test period. These changes in the patient's routine may provide false negative findings and adversely affect the reliability of the results.

Parents are also unhappy with these limitations. Some of our patients have refused to eat and drink properly and some missed school days while the pH probe catheter was in place.

Devices such as the Bravo™ pH Monitoring System (Medtronic, Inc. Shoreview, MN) may offer a more desirable diagnostic option for pH monitoring for pediatric patients and their

parents in terms of comfort and convenience. We are reporting our experience with Bravo™ capsule placement in children.

The purpose of this retrospective study is to analyze the efficacy, safety and reliability of the Bravo™ capsule placement procedure and its related complications.

MATERIALS AND METHODS

After obtaining Institutional Review Board approval, the records of all patients who underwent Bravo™ pH analysis from January 2002 to December 27, 2010 were reviewed.

As per our institute's upper gastrointestinal (GI) endoscopy protocol, all endoscopies were performed in the operating room and under general anesthesia. All patients were requested to stop proton pump inhibitors one week and if on H₂ receptors, two days prior to the procedure.

The procedure was discussed with patients and parents, and consent was obtained. Patients were told that they might feel some chest pain, pressure and discomfort after anesthesia or later during swallowing. Additionally, patients were told that it was not necessary to retrieve the capsule since it would fall spontaneously within a few days and pass through the gastrointestinal tract. The procedure was performed by using an Olympus GIF-160 gastrointestinal videoscope (Olympus, Center Valley, PA). The gastroesophageal junction was measured endoscopically, by the Strobel formula.³ The Bravo™ capsule was placed at 87% of the endoscopically determined distance from the incisor teeth to the Z line. This was about 6 cm above the gastroesophageal junction. A subsequent inspection using esophagoscopy was performed to confirm capsule attachment. Esophageal pH data was collected over a period of 48 hours. After the study was completed, our patients returned the recorder to the clinic. Patients or their parents maintained a daily log of meal and sleep times. Abdominal pain was

recorded with the Wong-Baker FACES Pain Rating Scale. A series of questions with yes and no responses for substernal or chest pain, dyspnea, dysphagia, odynophagia, vomiting, abdominal pain and gastrointestinal bleeding were asked. Parents and children were also asked to rank their activity level and overall satisfaction with the Bravo™ capsule test on a Likert scale ranking from 1 to 5. The data was downloaded via an infrared link to a computer using Polygram™ Net pH Analysis Software.

Results were analyzed with software package SPSS (version 14.0; SPSS, Chicago, IL) and the Mann-Whitney U test Minitab software (version 14; Minitab, State College, PA).

RESULTS

Within the past eight years a total of 219 patients (134 females and 85 males) were identified and their data evaluated. Mean age was 15 years (range: 6 to 18 years).

Indications for endoscopy and Bravo™ capsule placement were for evaluation of persistent epigastric abdominal or substernal pain, heartburn, GERD and chronic cough.

Bravo™ capsule was placed successfully in all patients. In two patients, a conventional pH catheter and Bravo™ capsule were placed simultaneously to compare the results.

Premature detachment was suspected in three patients (1.36%) due to sudden decrease of pH followed by an increase to a pH > 6. In these patients, abdominal X-rays showed the presence of the capsules in the patients' small bowels. These happened early in the study, when we had less experience with using the Bravo™ capsule. We did not notice it happening again after we learned how to deliver the capsule. One of these three patients had a simultaneous pH probe placement. In one patient (0.45%), malfunction of the recording device was detected although the patient tolerated the procedure very well. One of our patients (0.45%) deleted the data from the recording device and

another patient underwent placement of the Bravo™ capsule twice during five years. Except for these five patients, pH tracings for the remainder of patients were available for interpretation (Table 1).

Table 1: Malfunction of the Bravo™ capsule pH analysis

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|--|
| Total number of Bravo™ capsule placement = 219 |
| Premature detachment in 3 = 1.36% |
| Malfunction of recording device in 1= 0.45% |
| Data deleted by patient accidentally in 1= 0.45% |
| pH tracings available for interpretation in 214 patients |

There were no significant differences between the pH data obtained with the pH probe catheter and the Bravo™ capsule in our patients where the pH probe and Bravo™ capsule were placed simultaneously; however the tracing from the pH probe showed a slightly more alkaline pH.

In 3 out of 214 patients (1.45%), chest pain was reported only at mealtimes. One (0.45%) complained of chest, back and shoulder pain soon after Bravo™ capsule placement, while still in the recovery room. The patient's chest X-ray was normal and pain resolved after the first meal. During the study, a total of 9 out of 214 patients (4.2%) reported a sensation of the capsule in their chests without any pain at meals (Table 2). None of our patients reported vomiting, sore throat, dysphagia, feeling bad, refusal to go to school, or inability to eat regular meals in 48 hours of this study. No one had gastrointestinal bleeding or symptoms of gastrointestinal perforation. None needed to have the capsule removed because of pain or discomfort.

Table 2: Side effects of the capsule pH analysis

| | | |
|-----------------------|-----------------------|-------|
| Chest pain | 3 out of 214 patients | 1.4% |
| Chest and back pain | 1 out of 214 Patients | 0.45% |
| Esophageal discomfort | 9 out of 214 Patients | 4.2% |

DISCUSSION

GERD is an ongoing medical problem in pediatric and adult populations. One method for evaluation of reflux disease is endoscopy with biopsy. This provides information about any associated esophagitis. The use of a pH probe, Bravo™ wireless pH Monitoring System and impedance method measures both acid and non-acid reflux disease. The use of the impedance method is limited in children and mostly used in research studies.^{4,5} However, we have recently started this procedure in our institution in children.

The conventional pH probe test is very helpful and is the most reliable technique to evaluate the severity and frequency of GERD at any age. It is important to have this prognostic information for proper management of patients who remain symptomatic and it also gives us information in patients with extra gastroesophageal manifestation of reflux disease. This piece of information along with clinical and biopsy findings helps the physician to manage patients most effectively and assists with the decision to consider a Nissen fundoplication. In our practice, many patients have refused this test.

Some patients removed the probe just after it was inserted in the operating room under anesthesia, when moved to the recovery room, or soon after they arrived home. Removal is usually because the catheter causes local irritation and discomfort to the nasal area. Failures of the conventional pH probe test include wire breakage, failure to record, patient removal or the catheter coiling in the throat and mouth during a vomiting episode. Patient may modify their diet and daily physical activity or resting on a couch when a pH probe test is used. This gives false negative results, particularly in children and teenagers.

The Bravo™ capsule pH analysis was accepted and well tolerated in 93.9% of our patients. The catheter-free Bravo™ pH Monitoring System

collects pH data and transmits it via radio frequency. It is easy and takes only a few minutes to be placed following endoscopy, and gathers pH data for 48 hours. The patient remains on regular diet and normal activity. There is no associated throat or nasal discomfort.⁶

The capsule should be inserted at 6 centimeters above the gastroesophageal junction. There is a significant reduction in acid detection if it is placed at 10 centimeters when compared to 5 centimeters above the lower esophageal sphincter in patients with acid reflux disease.⁷ In adults the capsule has been introduced either orally or transnasally into the esophagus. The latter may cause nasopharyngeal irritation and bleeding. In children capsules should be inserted orally and by endoscopy.

Occasional un-attachment of the capsule is possible if the capsule hole does not touch the esophageal surface during suctioning time. With the Bravo™ capsule analysis, patients may present with substernal pain for only a short time. This will go away after the first or second meal. Proper explanation of the procedure, and patient awareness of possible short-term chest pain will reduce anxiety and lessen complaints in children and teenagers. We have suggested that patients consume regular meals and chew their food well, avoiding large bites and chunky food. This may be one of the reasons that our patients did well with no pain or odynophagia, due to the lack of pressure or stretching on the capsule by a large meal. It is possible that this prevents capsule detachment. It has been reported that 60% of patients with associated chest pain will have esophageal hypercontractibility when motility is performed with the Bravo™ capsule in place.⁸

After 48 hours, a follow up clinic visit was scheduled which was preferred by both patients and parents, mostly because patients were able to go to school and continue their regular work and activities without restrictions. In this study patients rarely complained of feelings of short

substernal pressure during swallowing. This pain and discomfort is due to esophageal contraction during swallowing episodes. We believe that feelings of pressure and chest pain should resolve after one or two meals.

We avoided Bravo™ pH analysis in patients with Crohn's disease, small bowel and esophageal stricture, because the capsule may not pass through the gastrointestinal tract. We did not insert the capsule in patients with severe erosive esophagitis due to poor attachment, and those with esophageal varices due to risk of bleeding, and in patients with intestinal pseudo-obstruction due to motility disorders.

Simultaneous recording of esophageal acid exposure with conventional pH monitoring and a wireless system have been performed in 40 patients suggestive of reflux disease. There was a significant correlation with the 24-hour esophageal acid exposure that was recorded. In this study, the Bravo™ catheter-free system under-recorded the acid exposure compared to the conventional pH probe test.^{9,10} Some have reported that the Bravo™ system detected fewer reflux events of short duration compared with a catheter-based system.¹¹ In our study, we had simultaneous conventional and Bravo™ pH analysis in two patients. In both, the acid recording was less with the Bravo™ system.

The Bravo™ wireless pH Monitoring System has been reported in adults to be safe, reliable, well tolerated and convenient for the patient.¹²⁻¹⁶ Our patients reported fewer complaints than others, possibly due to explanation of the procedure, their expectation of some discomfort and chewing modifications. Complications reported by others have been associated with nasal intubations for transnasal placement of the conventional catheter. Those include sore throat, and trauma to the naso-pharynx or bloody nose. For Bravo™ complaints include premature detachment of the capsule, failure of the capsule to slough in time and pain or discomfort associated with the capsule, requir-

ing endoscopic removal. In one study,¹⁷ four patients (3.4%) required upper endoscopy for removal of the pH capsule within 2 to 8 days of attachment because of severe pain upon swallowing. In our study none required capsule removal. Some patients may exaggerate the sensation of the capsule in the esophagus.

Upper pH monitoring of children with the Bravo™ pH capsule was evaluated in 25 children age 3 months to 11 years and revealed no serious complications.¹⁸ The test was done to evaluate patients with extra esophageal reflux disease that presented as asthma, croup, bronchitis, sinusitis, laryngomalacia, subglottic stenosis and reactive airway disease.¹⁹⁻²¹ Indications were vomiting and mostly pulmonary and sinus symptoms.²²

Non-endoscopic ambulatory transnasal placement of a wireless capsule for esophageal pH monitoring has been performed for feasibility, safety and efficacy in 39 adult patients.²³ In this study, 2 patients had epistaxis, 3 with laryngeal irritation and 20 had foreign body sensation in the chest. Endoscopic removal of the capsule was performed in some patients due to constant retrosternal pain.^{24,25} Another report of 85 adults noted that 3 (4%) required removal of capsule because of pain.¹²

Use of the Bravo™ pH Monitoring System has been approved for adults by the United States Food and Drug Administration. This is a significant advancement in the evaluation of patients with GERD because of potentially better tolerability and the ability to record data over a 48-hour period.

The Bravo™ pH capsule is easy to insert in children and they able to resume their normal activities without missing school and work. This test is safe and more informative because of a 48-hour recording period compared to 24 hours by the conventional pH probe test. Patient satisfaction was 96.26% in our study with no associated complications or serious problems. The Bravo™ pH Monitoring System is

a safe, reliable, and effective diagnostic tool with good tolerance for pediatric patients suspected of suffering from GERD. This test offers a more comfortable and convenient testing option.

CONFLICT OF INTEREST

The authors declare no conflict of interest related to this work.

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