

ASGE Technology Status Evaluation Report: wireless esophageal pH monitoring system

INTRODUCTION

To promote the appropriate use of new or emerging technologies, the American Society for Gastrointestinal Endoscopy Technology Committee has developed a series of status evaluation papers. This process presents relevant information about these technologies to practicing physicians for the education and the care of their patients. In many cases, data from randomized controlled trials are lacking, and only preliminary clinical studies are available. Practitioners should continue to monitor the medical literature for subsequent data about the efficacy, the safety, and the societal and economic aspects of the technologies.

BACKGROUND

GERD is characterized by pain and by mucosal inflammation caused by prolonged exposure of the esophageal mucosa to gastric acid. The frequency and the cumulative duration of esophageal-acid exposure over 24 hours provides a measure of the severity of gastroesophageal reflux.¹ Ambulatory esophageal pH studies for 16 to 24 hours are indicated in patients with symptoms suspected to be caused by gastroesophageal reflux.^{2,3} Traditional catheter-based assessment of 24-hour esophageal pH has significant limitations because of patient discomfort and resulting modifications in their diet and activity or premature removal of the catheter.^{4,5} A wireless system for prolonged monitoring of intraesophageal pH (Bravo System; Medtronic Inc, Shoreview, Minn) is now available.^{6,7,8} This status evaluation report addresses the use of the Bravo System for investigation of suspected reflux disease.

TECHNOLOGY UNDER REVIEW

The Bravo System includes the prepackaged Bravo pH Capsule with Delivery System, a calibration stand, a pH receiver, the Datalink (Medtronic) cradle for downloading of data, calibration solutions (pH 7.01 and 1.07), and software

(POLYGRAM NET pH Testing Application) (Medtronic). The system is compatible with Windows 95/98/2000, NT, or XP (Microsoft Corp, Redmond, Wash) and can be purchased in a package with a desktop or a notebook computer.

The Bravo pH monitor is an oblong (6 × 5.5 × 25 mm) plastic capsule that houses an antimony pH electrode and a reference electrode located on its distal tip, a battery, and a transmitter. The electronics and the sensor are all encapsulated in epoxy. The capsule is affixed to the esophageal mucosa at the time of upper endoscopy. The capsule continuously senses the distal esophageal pH and transmits the data via radiotelemetry to a pager-sized receiver worn by the patient.^{6,7,8} The carrier frequency of the pH signal is in the unregulated 433-MHz band. Data security is accomplished by digital data transmission and by encoding each capsule with a unique identification code that is transmitted every 12 seconds, along with two pH data points obtained at 6-second sampling intervals.

The delivery system is designed for either oral or nasal passage. Its components include a leading end for attachment to the capsule, a tubular midsection (80-cm long, 6F diameter), and a handle with a suction port. During deployment, the delivery system transmits 600 mm Hg of vacuum pressure to a 4 × 3.5-mm mucosal attachment well on the superior-lateral aspect of the capsule.

Technique

Before placement, the capsule is activated by removal of an attached magnet and is calibrated by submersion in pH buffer solutions of pH 7.0 and pH 1.07 (Medtronic). The user is guided through this process by a light-emitting diode readout on the data receiver. In the process, the capsule and the receiver also are checked to confirm proper functioning of data transmission and receiving hardware.^{6,7,8}

Patients undergo upper endoscopy, with standard moderate sedation, to identify pathology or altered anatomy and to measure the distance between the gastroesophageal junction and the incisors. After the completion of upper endoscopy, the endoscope is removed, and the delivery system is passed into the esophagus via either the mouth (most common) or the nares. Endoscopic measurements are used to position the pH capsule 6 cm above the squamocolumnar junction,⁴ which corresponds to conventional placement 5 cm proximal to the upper

margin of the lower esophageal sphincter (LES).^{6,7,8} The pH capsule also can be placed without prior endoscopy by using manometric localization of the LES.

With the delivery system in the desired location, the external vacuum pump is activated to apply suction to the well of the pH capsule, pulling the adjacent esophageal mucosa into the fastening well. Successful capture of esophageal mucosa is presumed when the vacuum gauge on the pump stabilizes at >510 mm Hg for 10 seconds. The plastic safety guard on the handle then is removed, and the activation button is depressed and turned. This deploys a spring-loaded, stainless-steel pin that is driven through the mucosa within the well of the pH capsule, ensuring attachment of the pH capsule to the esophageal wall. The activation button on the handle then is twisted clockwise 90° and re-extended, releasing the pH capsule from its attachment point on the delivery system. The delivery system is rotated off the capsule and removed. Esophagoscopy may be repeated to document capsule attachment, with care not to dislodge the capsule. Once the capsule is attached, pH recording is initiated.^{6,7,8}

Recording protocol

Bravo pH studies are capable of detection, transmission, and storage of pH data up to 48 hours. Patients are encouraged to engage in their usual daily activities and to consume their usual diet. There are no dietary guidelines; however, the dietary stimulus of at least one high-fat meal each day is occasionally advised. Consumption of caffeinated, carbonated, or alcoholic beverages is neither encouraged nor prohibited. Patients are asked to keep a diary that documents food intake, sleep intervals, and occurrence of symptoms. Reflux-related symptoms or other events can be documented by activating a button on the external recorder. When showering, patients are instructed to leave the data receivers outside but close to the shower. The maximal range for successful transmission and reception is 3 to 5 feet.^{6,7,8}

Data analysis

When recording is completed, the pH study data are uploaded to a computer via the proprietary cradle and software (Datalink). Temporal data that pertains to food intake, symptoms, and supine periods are extracted from the patients' dairies and are manually entered to incorporate them with the computer-recorded pH and event data. A summary report then is generated by using the POLYGRAM NET pH Testing Application Software (Medtronic). It includes a graphical pH tracing; statistics on the total and the percentage of time with pH < 4.0; the longest episode during which pH is < 4.0; the total number of reflux episodes; the number of episodes during which the pH was < 4 for 5 minutes or more; the total duration of pH recording; the total and percentage time with upright, supine, and postprandial reflux^{6,7,8}; and a calculated DeMeester score.

EFFICACY AND SAFETY

After successful deployment, satisfactory recording of esophageal pH is accomplished in 98% of cases with the current design. Premature dislodgment with prolonged intragastric recording occasionally is seen. Overall success during 1- and 2-day studies is 96% and 89%, respectively.⁷ A small pilot study demonstrated comparable results in patients evaluated with both Bravo and standard transnasal 24-hour PH studies.⁹ The data for evaluating the ability of the wireless pH system to discriminate patients with endoscopy-negative GERD from controls also is similar to previous reported studies.^{6,7,8}

The pH capsules generally are well tolerated. Most patients note a mild foreign-body sensation, especially while eating. Clinical experience suggests that a small proportion of patients may experience odynophagia and/or chest pain. Patients should be cautioned about this possibility. No serious complications have been reported among 110 patients. Failure of attachment (3.4%), irreversible failure of data retrieval (1.7%), and failure to spontaneously detach within 14 days (6.8%) have all been reported.^{7,8}

The presence of a cardiac pacemaker currently is a contraindication to wireless pH recording with the Bravo System because of potential problems with signal interference and corruption or loss of data. Proprietary testing of pacemaker interaction with the function of the Bravo System is pending Food and Drug Administration submission.

FINANCIAL CONSIDERATIONS

The list price of the single-use Bravo capsule with delivery device is \$225. In comparison, traditional transnasal pH catheters cost \$62. The list price for the multiuse Bravo receiver is \$6900. The complete system (Bravo-in-a-Box), which includes two Bravo pH receivers, POLYGRAM NET pH Testing Application Software, Datalink, a calibration stand, a vacuum pump, calibration buffer pH 7.01 and 1.07, a 4-pack of AA lithium batteries, a dedicated notebook computer, and HP Desk Jet color printer) is approximately \$25,704. The complete price lists for individual components and the entire Bravo System are provided in Table 1. As of January 1, 2005, telemetry-based pH monitoring for gastroesophageal reflux testing should utilize current procedural terminology (CPT) code 91035. This code is not on the Medicare-approved ASC list, so providers should contact their local Part B carrier. For outpatient hospital facilities, CPT code 91035-26 is appropriate, along with the Ambulatory Payment Classification (APC) New Technology code 1506.

CONCLUSIONS

Wireless esophageal pH monitoring offers a safe and a more comfortable alternative to pH monitoring by

TABLE 1. Bravo pH Monitoring System components and costs

Description	Price (\$)
Bravo pH capsule with delivery system (box of 5)	1125
AA lithium batteries (pack of 4)	15
Bravo pH receiver	6,900
Calibration buffer pH 1.07 (500-mL bottle)	22
Calibration buffer pH 7.01 (500-mL bottle)	22
Bravo Kit (includes two Bravo pH receivers, Datalink, calibration stand, vacuum pump, calibration buffer pH 7.01 and 1.07, 4-pack AA lithium batteries)	16,649
Bravo Kit with software (includes 2 Bravo pH receivers, POLYGRAM NET pH Testing Application Software, Datalink, calibration stand, vacuum pump, calibration buffer pH 7.01 and 1.07, 4-pack of AA lithium batteries)	22,149
Bravo Kit Software and Workstation (includes 2 Bravo pH receivers, POLYGRAM NET pH Testing Application Software, Datalink, calibration stand, vacuum pump, calibration buffer pH 7.01 and 1.07, 4-pack AA lithium batteries, Gastro Workstation, Standing)	28,139
Bravo-in-a-Box (includes 2 Bravo pH receivers, POLYGRAM NET pH Testing Application Software, Datalink, calibration stand, vacuum pump, calibration buffer pH 7.01 and 1.07, 4-pack AA lithium batteries, dedicated notebook computer, HP Desk Jet color printer)	25,704
Filter	4.50
System tubing (canister-to-filter)	6
Patient tubing (Bravo delivery system-to-filter)	4.50

conventional transnasal systems. Patients generally are able to maintain normal activity and dietary intake during the study. A pilot study that evaluated simultaneous catheter-based pH monitoring and Bravo pH monitoring revealed that the two techniques were comparable in quantifying esophageal-acid exposure. The normal values for esophageal pH exposure during wireless monitoring need to be confirmed.

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