

## **Abstracts: Clinical Benefits of Bravo pH System**

### **Utilizing the BRAVO™ Esophageal PH Monitoring System to Compare PH Profiles in GERD Patients and Healthy Adult Volunteers**

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Current diagnosis of gastroesophageal reflux disease (GERD) employs a 24-hr ambulatory pH study with a nasal probe. However this method frequently hinders patients from following their typical activities of daily living, potentially interfering in test accuracy and reproducibility. The Bravo Esophageal pH Monitoring System is a miniature data radio transmitting (48-hour capability) catheter-free capsule attached by endoscopy to the esophageal mucosa 6cm above the LES that sloughs off and passes spontaneously over time.

**AIM:** Evaluate the effectiveness of the new Bravo system with regards to: 1) distinguishing previous diagnosed GERD patients from healthy volunteers and 2) comparing acid reflux data in the first vs. second 24hr period for diagnostic accuracy in GERD patients.

**METHODS:** Twenty-two subjects were prospectively evaluated using the Bravo system. Eleven GERD (8 male, 3 female, mean age 52 yrs) had previous abnormal 24-hr ambulatory pH studies and 8 of 11 had prior endoscopic esophagitis and/or Barrett's esophagus. Eleven controls (3 male, 8 female, mean age 40 yrs) had no history of heartburn or use of antacid drugs. Bravo capsule placed the afternoon of day 1 with meperidine/midazolam conscious sedation. Total, upright, and supine % time pH <4 values were compared between groups and within first and second 24hrs of GERD patients using the Mann-Whitney Rank Sum Test.

**RESULTS:** Bravo pH data significantly ( $p < 0.05$ ) separated known GERD patients from controls based on second 24hr group analysis (median upright and supine % time pH <4 was 9.3 & 9.5 respectively for GERD and 0.08 & 0.0 respectively for controls). The second 24hr data properly diagnosed known GERD patients in one or more pH values (total, upright, supine) in 9 of 11 (82%), an improvement from 6 of 11 patients (55%) in the first 24hrs.

**CONCLUSIONS:** Gastroesophageal reflux values obtained by the Bravo system accurately distinguished GERD patients from controls. The second 24hr Bravo pH data is more reliable for overall classification of GERD. This phenomenon is likely related to the impairment of regular activity and meals as a carry-over of conscious sedation during the first 24hrs.

**Bravo PH vs Ambulatory 24 Hour Catheter PH Monitoring: A Prospective Assessment of Patient Satisfaction, Discomfort and Impairment of Daily Activities**

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Ambulatory 24-hr pH monitoring via a nasal catheter is currently the gold standard for measuring esophageal pH. However, it has a 70% sensitivity rate due to limitations on patients’ regular activity level. The Bravo pH monitoring system utilizes a catheterless system that monitors esophageal pH via a radio-transmitted capsule endoscopically attached to esophageal mucosa.

**AIM:** Compare ambulatory catheter pH monitoring to the Bravo pH system for satisfaction, discomfort and ability to carry out activities of daily living in both GERD subjects and healthy volunteers.

**METHODS:** Twenty-two subjects (11 GERD, 11 controls) had endoscopic placement of Bravo pH capsule followed by 48 hr pH monitoring. Additionally, 30 consecutive age and gender matched symptomatic patients underwent traditional ambulatory esophageal 24-hr pH testing with a nasal catheter. Subjects completed a self-administered questionnaire addressing demographics, satisfaction, discomfort, and activities of daily living (diet, sleep, activity level) after completion of pH testing.

**RESULTS:** Mean ( $\pm$ SE) satisfaction with Bravo vs. catheter testing was  $0.8 \pm 0.1$  vs.  $1.9 \pm 0.2$ , respectively based on a six-point visual scale (0=very satisfied) ( $P=0.001$ ). Discomfort associated with Bravo vs. catheter pH patients: no discomfort (8/22 vs. 4/30, NS), throat discomfort (4/22 vs. 22/30,  $p<0.001$ ), and esophageal discomfort (10/22 vs. 5/30,  $p=0.05$ ). Esophageal discomfort in Bravo group was significantly more common in the health controls (9/11) than the GERD subjects (1/11) ( $p=0.008$ ). Percentage of patients reporting changes in daily activities due to pH monitoring system shown in Table. No serious complications noted with either pH system.

**CONCLUSIONS:** Compared to traditional pH testing, Bravo system causes significantly less throat discomfort and impairment of daily activities. Healthy volunteers noted some esophageal discomfort but this was not a problem for GERD patients.

	Daily Routines	Diet	Sleep	Activity Level
Bravo	0/22 (0%) $p=0.001$	1/22 (5%) $p=0.001$	2/22 (9%) NS	0/22 (9%) $p<0.001$
Catheter	11/30 (37%)	14/30 (47%)	9/30 (30%)	18/30 (60%)
Fisher Exact				

## **The BRAVO™ pH capsule: Clinical evaluation of a catheter-free ambulatory esophageal pH monitoring system**

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**Background:** Ambulatory 24-hour esophageal pH monitoring is currently the most accurate test for determining the presence of gastroesophageal reflux disease and the best discriminate for a good outcome from anti-reflux surgery. It is performed using an indwelling esophageal catheter passed through the nose. Patients commonly complain of nasal and pharyngeal discomfort, rhinorrhea, and social embarrassment. The BRAVO™ pH system avoids these problems by using a catheter-free capsule, which is temporarily attached to the esophageal mucosa. The capsule delivery, attachment and detachment were studied and the adequacy of pH transmission and reception evaluated. Comparison of data collection and morbidity between the pH catheter and BRAVO™ capsule was made.

**Methods:** Asymptomatic volunteers were randomized to receive either a BRAVO™ capsule alone, or a BRAVO™ capsule and a conventional pH catheter. Each was positioned 5cm above the proximal border of the lower esophageal sphincter. Conventional catheters were monitored for 24 hours and BRAVO™ capsules for 48 hours.

**Results:** Transnasal delivery of the BRAVO™ capsule was achieved in 95%, successful esophageal attachment in 98%, and all detached by day 12. Signal reception was 96%. The capsule-only group experienced significantly less disruption to daily activities and fewer side effects than the group receiving both a capsule and a catheter. Similar pH results were measured by both techniques.

**Conclusions:** The BRAVO™ catheter-free system is comparable to the conventional catheter for quantifying esophageal pH, but its greater comfort should lead to increased patients compliance during testing prior to surgical therapy.

**Comparison of Normal Values Obtained with the BRAVO™, a Catheter-Free System, and Conventional Esophageal pH Monitoring**

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Background: Conventional pH monitoring, using a naso-esophageal catheter, is the gold standard in the diagnosis of GERD, the strongest predictor of surgical success and the best quantitative measurement of treatment outcome. Its disadvantage is patient discomfort. The recent BRAVO™ capsule avoids the nasoesophageal catheter leading greater patient acceptance.

Aim: To compare the concordance of the pH data from the BRAVO™ capsule with the established values in normal subjects using a conventional catheter.

Methods: 20 asymptomatic volunteers underwent a videosophagram and esophageal manometry to exclude motor disorders or anatomic abnormalities. PH monitoring was performed using the BRAVO™ capsule with antimony sensor placed transnasally 5 cm above the proximal border of the manometrically determined lower esophageal sphincter. Data were transmitted to a portable receiver via radio frequency over 48 hours. Patient tolerance was evaluated using a clinical questionnaire.

Results: The capsule was well tolerated and all subjects completed the study successfully. All capsules were detached in 12 days. BRAVO™ pH data for the first 24 hours are shown in the table, compared to normal values established for the conventional catheter.

	BRAVO™ N=20	Conventional pH N=50	P Value
% total time pH<4	2.6±1.6	1.5±1.4	0.005
% upright time pH<4	3.0±2.1	2.3±2.3	ns
% supine time pH<4	1.8±4.0	0.6±1.0	ns
Longest reflux episode	7.6±7.2	6.7±7.9	ns
Number of reflux episodes >5 min	1.1±1.7	0.8±1.2	ns
Number of reflux episodes	35.2±21.0	19±12.8	0.0002
DeMeester score	6.0±4.3	6.0±4.4	1
DeMeester score (95 <sup>th</sup> percentile)	12.9	14.7	/

Conclusions: The BRAVO™ is well tolerated, but records statistically different values of % total time pH<4 and number of reflux episodes. However, the DeMeester score

calculated with BRAVO™ system is comparable to normal established values for the conventional catheter.

### **Esophageal pH Monitoring Using a Catheter-Free pH-System (Bravo pH System™)**

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**Background:** The main limitations of catheter based esophageal pH monitoring are discomfort, inconvenience and interference with normal activity. An alternative to conventional pH monitoring is the catheter-free Bravo pH System. The aim of this study was to develop a normal data set for asymptomatic controls and GERD patients using the Bravo System. **Methods:** 34 healthy normal subjects (8 male, ages 21-51) and 27 GERD patients (15 male, ages 22-72) were studied for a two day period consuming a diet that included one fatty meal each day. After calibration, the pH capsule was positioned transorally 6 cm above the squamocolumnar junction using endoscopy for measurement. The signal transmitted from the capsule was received and recorded by a small pager sized receiver worn by the patient and subsequently uploaded to a computer for analysis. **Results:** During the two day period the median % pH < 4 was 2.42 (95% CI, 0.41-5.74) in normal subjects and 7.17 (95% CI, 3.51-19.08) in GERD patients. There was a significant difference between the mean total number of reflux events (p=0.002) of normal subjects and GERD patients. Successful recordings of >24 hours were achieved in 58 of 61 subjects (95%). Two failures occurred due to premature capsule detachment and one failure due to poor data capture. Bravo capsules needed to be endoscopically removed in 3 subjects (5%); 2 because of discomfort and 1 because of failure to spontaneously detach after 14 days. Early data reception was 91%, but subsequently improved to 98% with product improvement including an addition of a 7-inch receiver antenna. In addition, it appeared that there was benefit to monitoring patients for 48 hours (Table). Ten of the 24 GERD patients had abnormal acid exposure on one day and normal acid exposure on the other day (5 subjects were abnormal day 1 and normal day 2; 5 subjects were normal day 1 and abnormal day 2). Only 3 GERD patients had normal acid exposure on both days. **Conclusion:** The catheter-free Bravo pH System successfully recorded esophageal acid exposure in 95% of the patients during a 24 hour period. The normal values that we report appear to be similar to previously reported data. In addition, our study also revealed that accuracy may be improved by monitoring patients for 48 hours.

	Normal Subjects (n=28)		GERD Patients (n=24)	
	% Time pH	# of subjects with pH % time > 5.74	% time pH	# of subjects with pH % time < 5.74
1st 24 hours	2.48 (0.37-6.49)	2	7.56 (2.37-15.59)	8
2nd 24 hours	1.83 (0.21-7.57)	2	8.92 (1.11-23.73)	8
Combined	2.42 (0.41-5.74)	1	7.17 (3.51-19.08)	7