

Does deep sedation impact the results of 48 hours catheterless pH testing?

Vineet Korrapati, Jay P Babich, Anil Balani, James H Grendell, Kavita R Kongara

Vineet Korrapati, Jay P Babich, James H Grendell, Kavita R Kongara, Department of Gastroenterology and Hepatology, Winthrop University Hospital, Mineola, NY 11501, United States
 Anil Balani, Department of Gastroenterology and Hepatology, UMDNJ-RWJ Medical School, New Brunswick, NJ 08901, United States

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Correspondence to: Dr. Vineet Korrapati, MD, Department of Gastroenterology and Hepatology, Winthrop University Hospital, 222 Station Plaza-Suite 428, Mineola, NY 11501, United States. vkorrapati@winthrop.org

Telephone: +1-516-6632066 Fax: +1-516-6634655

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Abstract

AIM: To study a cohort of patients undergoing 48 h Bravo pH testing receiving deep sedation with propofol.

METHODS: We retrospectively reviewed the charts of 197 patients (81 male, 116 female) who underwent Bravo esophageal pH monitoring from July 2003 to January 2008. All patients underwent Bravo pH probe placement *via* esophagogastroduodenoscopy (EGD) and received propofol for sedation. Patients on a proton pump inhibitor (89 patients) were excluded. Acid reflux variables measured included the total, upright, and supine fractions of time at pH < 4 and DeMeester score, and were compared between day 1 and day 2.

RESULTS: Of the 108 patients that were included in the study, the most common indication for Bravo pH monitoring was heartburn, with chest pain being the second most common. A signed rank test revealed no

statistically significant difference between day 1 and day 2 reflux episodes.

CONCLUSION: Patients who received propofol for sedation for EGD with Bravo pH capsule placement did not experience any significant difference in reflux episodes from day 1 to day 2.

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Key words: Esophagus; Bravo study; Propofol; pH capsule; Gastroesophageal reflux disease

Peer reviewer: Helena Nordenstedt, MD, PhD, Upper Gastrointestinal Research, Department of Molecular Medicine and Surgery, Karolinska Institute, Stockholm 17176, Sweden

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INTRODUCTION

Esophageal pH monitoring is widely used for the diagnosis of gastroesophageal reflux disease (GERD). Some indications for monitoring, as defined by expert panels, include refractory symptoms or continuation of atypical symptoms despite proton pump inhibitor (PPI) treatment, evaluation for anti-reflux surgery and recurrence of symptoms following anti-reflux surgery^[1-3].

Traditionally, the transnasal placement of a pH catheter probe was used to monitor esophageal pH. This technique often produced discomfort, inconvenience and often restricted activity and diet, thereby underestimating the amount of reflux^[4]. The limitations of the conventional catheter system (CCS) led to the development of a

catheter-less system (CLS) which utilizes a radiotelemetry pH-sensing capsule clipped to the esophageal wall. Compared to CCS, CLS is better tolerated by patients and permits increased duration of pH recording^[5].

Despite the wide use of the CLS, there have not been any standardized guidelines for the placement of the catheter. For example, the Bravo capsule may be clipped to the esophagus on the same day as esophagogastroduodenoscopy (EGD) with sedation or on a different day, with or without sedation.

Studies in the past on the CLS, have examined the differences in day 1 (d1) and day 2 (d2) with limited sample sizes and varied results. A few have suggested that a probable cause of increased reflux episodes on d1 may be the effect of sedation. Until now, there has been limited data examining the effect of deep sedation on d1 and d2 results.

MATERIALS AND METHODS

We retrospectively reviewed the charts of 197 patients who underwent 48-h Bravo pH monitoring (Medtronic) for suspected GERD over a 5-year period at Winthrop University Hospital. This study was approved by the Institutional Review Board of our institution. Eighty nine patients who were on anti-reflux medications at the time of the study were excluded.

All patients that were included in the study underwent EGD under deep sedation (propofol) with placement of the capsule at the time of the procedure. All patients underwent EGD with Bravo placement by the same endoscopist (KRK). The capsule was placed at 6 cm above the gastroesophageal junction. Following deployment of the capsule, accurate placement was confirmed with direct visualization. Following recovery from sedation, patients were instructed to keep the data recorder around their waist and were encouraged to resume their normal daily activities and usual diets. Patients were also instructed to keep a diary of daily activities (e.g. when they ate, periods of sleep), and occurrence of symptoms.

Patients returned 48 h later and turned in their receivers and diaries. The data was downloaded and analyzed by Medtronic software, which then generated a summary report, which was reviewed by one gastroenterologist (KRK). The summary report included percent of total time at pH < 4, percent of upright time at pH < 4, percent of supine time at pH < 4, total number of reflux episodes and the DeMeester score.

Statistical methods

All continuous variables were summarized using mean \pm SD. We calculated delta scores of our parameters, representing the difference from d1 to d2, i.e. to determine the effects of deep sedation. Since these difference scores were not normally distributed, we utilized the signed-rank test (instead of the paired *t*-test for normally distributed difference scores) to assess the statistical significance of these differences. All calculations were performed using SAS 9.1 for Windows (SAS Institute, Cary,

Table 1 Indication for Bravo monitoring

Indication	Frequency	Percent (of <i>n</i> = 108)
Heartburn	63	58.30%
Chest pain	32	29.60%
Chronic cough	9	8.30%
Laryngitis	23	21.30%
Bloating	38	35.20%

Total percentages exceed 100% since about half of the patients had two distinct indications.

NC, USA); results were considered significant when *P* < 0.05.

RESULTS

Our analysis included 108 patients (47 male, 61 female; mean age \pm SD, 54.74 \pm 14.67) after excluding 89 patients on anti-reflux medications. Table 1 shows the indications for Bravo pH monitoring. The most frequent indication was heartburn (58% of the patients) followed by chest pain. The total percentages in Table 1 exceed 100% since about half of the patients presented with two indications for the study.

Tables 2-5 indicate descriptive statistics for each of our parameters for d1, d2, and delta = d2-d1. None of the difference scores were significantly different from zero by the signed rank test, although one parameter (upright) showed a trend toward significance (*P* = 0.0576).

DISCUSSION

GERD is defined as symptoms or mucosal damage produced by the abnormal reflux of gastric contents into the esophagus^[3]. The typical clinical manifestations include heartburn and regurgitation; however an atypical presentation should be considered when chronic cough, non-cardiac chest pain, and otolaryngological (ENT) symptoms are present. It is appropriate to offer empiric therapy with a PPI to patients with symptoms consistent with GERD. However symptoms that are refractory to high-dose PPI would usually prompt the clinician to perform an endoscopy. The majority of symptomatic patients will have a normal endoscopy which does not necessarily indicate either less severe symptoms or a more easy to control form of GERD^[6].

Studies demonstrate that those GERD patients without esophagitis have symptoms that are just as difficult and at times more difficult to control^[7]. The diagnosis of GERD in the symptomatic patient without endoscopic findings requires prolonged ambulatory pH monitoring. This technique assesses the magnitude of esophageal acid exposure, and also allows one to assess whether a correlation exists between symptoms reported by the patient and acid reflux events^[8]. The only way to perform ambulatory pH monitoring, up until recently, has been by the transnasal placement of a pH catheter probe left in

Table 2 Time pH < 4 - upright (%)

	Mean	Median	SD	Minimum	Maximum
Day 1 (d1)	7.31	5.70	7.55	0	41.4
Day 2 (d2)	6.52	4.85	7.89	0	59.6
Delta = d2-d1	-0.79	-0.50	5.81	-19.9	24.8

Mean Delta (-0.79) not significantly different from zero ($P = 0.0576$) by signed rank test.

Table 4 Time pH < 4 - total (%)

	Mean	Median	SD	Minimum	Maximum
Day 1 (d1)	6.36	4.85	7.60	0.0	48.1
Day 2 (d2)	6.02	4.25	8.02	0.0	67.1
Delta = d2-d1	-0.34	0.00	6.13	-22.5	29.6

Mean Delta (-0.34) not significantly different from zero ($P = 0.73$) by signed rank test.

place for 24 h. Patients often alter their daily physical and dietary activities, or do not complete the study, as they find a transnasally placed pH electrode conspicuous and uncomfortable. These changes result in “false negative” results if the activity and/or dietary limitations reduce esophageal acid exposure to within the normal limits^[4].

The Bravo pH monitoring system is a newer modality in which a pH-sensing capsule is endoscopically clipped to the esophageal wall, and transmits pH data to a recorder worn by the patient. Bravo esophageal pH monitoring is better tolerated by patients and permits increased duration of pH recording compared to the traditional catheter-based pH system^[9].

Many studies have been performed to investigate if a difference exists for gastroesophageal reflux as measured by the Bravo pH system between d1 and d2 of the study. The results have been somewhat conflicting. In a study performed by Bhat *et al*^[10], 217 patients underwent endoscopy and capsule placement. Of these, 56% were abnormal with 32.2% being abnormal on both days, and showed increased acid exposure on d1 compared to d2. The higher likelihood of abnormal results for d1 was associated with a significantly increased esophageal acid exposure during the first 6 h after capsule insertion on d1 compared with the corresponding time on d2 without differences in esophageal acidification during the remaining time or differences in recorded activity. The significantly higher likelihood of abnormal findings during the initial period of pH monitoring suggests an influence of endoscopy and associated sedation, typically performed prior to capsule insertion, which needs to be considered when pH data are analyzed^[10]. Bechtold *et al*^[11] performed a retrospective review on 27 consecutive adult patients who underwent Bravo pH monitoring with intravenous doses of midazolam and fentanyl. Their results demonstrated that people with moderate conscious sedation experience significantly more acid reflux on d1 than d2.

Other studies performed have reported no consistent differences. Pandolfino *et al*^[12] found no differences

Table 3 Time pH < 4 - supine (%)

	Mean	Median	SD	Minimum	Maximum
Day 1 (d1)	4.01	0.25	8.94	0.0	60.2
Day 2 (d2)	4.66	0.00	12.20	0.0	87.4
Delta = d2-d1	0.65	0.00	11.80	-33.1	63.3

Mean Delta (0.65) not significantly different from zero ($P = 0.56$) by signed rank test.

Table 5 DeMeester score

	Mean	Median	SD	Minimum	Maximum
Day 1 (d1)	22.0	16.3	25.7	0.0	163.7
Day 2 (d2)	21.1	15.2	25.6	0.0	213.0
Delta = d2-d1	-0.9	0.0	21.0	-100.5	82.2

Mean Delta (-0.9) not significantly different from zero ($P = 0.90$) by signed rank test.

between d1 and d2 in their patients who underwent same day EGD with 50 to 75 mg of meperidine and 1 to 5 mg of midazolam. Prakash *et al*^[13] evaluated patients who underwent endoscopic placement of a wireless capsule with conscious sedation, employing a variety of different medications at the time of Bravo placement, and found no differences in reflux variables between d1 and d2.

The limitations of our study include the fact that it was retrospective and that a variety of different anesthesiologists administered the anesthesia. However, all Bravo placements and interpretations were performed by the same gastroenterologist.

In conclusion, there is great variability in different studies between the number of reflux episodes from d1 to d2. However, this was not demonstrated in our study when looking at patients undergoing deep sedation with wireless ambulatory esophageal pH monitoring, thereby supporting deep sedation as the optimal method for patient comfort and accuracy of data. Future prospective studies looking at larger sample sizes are needed to substantiate our findings.

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COMMENTS

Background

The prevalence of esophageal pH monitoring for the diagnosis of gastroesophageal reflux disease (GERD) has increased substantially. Despite its widespread use, there are no standard guidelines for the placement of the catheter.

Research frontiers

Some studies in the past have suggested that the effects of sedation used during placement of a 48 h catheter-less pH monitoring device may account for the difference in day 1 (d1) to day 2 (d2) data. In this study, the authors demonstrate that using deep sedation in the placement of a wireless pH monitoring device reduces the difference in d1 and d2 data.

Innovations and breakthroughs

Many studies have been performed to investigate if a difference exists for gastroesophageal reflux as measured by the Bravo pH system between d1 and d2 of the study. The results are conflicting. This study suggests that deep sedation may eliminate the variability in data from d1 to d2.

Applications

By using deep sedation during placement of a catheter-less pH monitoring device, the authors could limit the number of false positive results (i.e. acid reflux episodes) during d1.

Terminology

Bravo is a catheter-less pH monitoring device that is endoscopically clipped to the esophageal wall, and the data is transmitted to a recorder worn by the patient.

Peer review

This is an interesting study, delving into how to best use the Bravo capsule. Disadvantages include (as the authors state) that it is a retrospective study. Since there is no comparison group in the study either, it is difficult to generalize this study to other settings.

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