Bravo® Wireless pH Monitoring

Title
Prolonged, Wireless pH Studies Have a High Diagnostic Yield in Patients With Reflux Symptoms and Negative 24-h Catheter Based pH Studies

Key Points

1. In this trial, 38 patients with continuing reflux symptoms despite negative 24-h catheter-based studies repeated pH studies using Bravo capsules for a prolonged, study monitoring up to 96 hours.

2. More than half of patients (61%) received a positive diagnosis of GERD based on average esophageal acid exposure and cumulative reflux symptom association. The yield increased further (76%) if diagnosis was based on “worst day” analysis.


4. This study suggests that if a false-negative diagnosis is suspected, especially if there is a suggestion of modified behavior due to catheter discomfort, prolonged wireless pH studies should be considered.
A modest increase of diagnostic yield occurs comparing 48 hour studies to 96 hour studies when using “average” and/or “worst day” analysis.

Abstract

**Background** Catheter-based esophageal pH-monitoring is used to evaluate patients with suspected gastroesophageal reflux disease (GERD); however false-negative results may occur due to poor tolerance of the catheter with reduced oral intake and activity, or high day-to-day variation in reflux and symptom events. We assessed diagnostic yield and clinical impact of prolonged, wireless pH-monitoring in patients with negative results from 24-h catheter-based studies and ongoing symptoms.

**Methods** Esophageal acid exposure (percentage time pH <4), Symptom Index, and Symptom Association Probability (SAP) were calculated. Diagnostic yield was assessed using Average (mean) and Worst Day (24-h period with highest acid exposure or symptom load) analyses. Outcome data were assessed 6–36 months (median 24) after initiation of definitive therapy based on physiologic testing.

**Key Results** Data from prolonged pH-monitoring up to 96-h (median 72-h) were available from 38 patients. Using Average and Worst Day analysis, esophageal acid exposure was pathologic in 37% and 47%, whereas SAP was positive in 34% and 63% of patients, respectively. Overall using Average and Worst Day analyses, 61% and 76% patients were diagnosed with GERD based on either pathologic acid exposure or positive symptom association. Of 12 patients that underwent antireflux surgery, 10 (83%) reported a good outcome at a median 24 months follow-up.

**Conclusions & Inferences** Prolonged, wireless pH-monitoring increases test sensitivity and diagnostic yield in patients with continuing esophageal symptoms despite negative 24-h catheter-based pH-studies. Without a definitive diagnosis, many would not have received effective treatment.