Clinical paper

Medtronic provides the following synopsis of a clinical publication involving the Bravo Reflux System.

TITLE Prolonged Wireless pH Monitoring in Patients With Persistent Reflux Symptoms Despite Proton Pump Inhibitor Therapy

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INTRODUCTION

Ambulatory reflux monitoring is used to quantify esophageal acid burden in patients with persisting symptoms despite PPI therapy and inconclusive endoscopic findings. Wireless pH monitoring permits prolonged (greater than 48 hours) evaluation of reflux burden inclusive of daily fluctuations in acid exposure. The most appropriate method of analyzing prolonged pH data has yet to be determined.

PURPOSE OF THE STUDY

The primary aim of this study was to evaluate interpretation paradigms including averaged total Acid Exposure Time and predominant AET pattern for prolonged pH monitoring beyond 48 hours in patients with reflux symptoms but poor PPI response, compared to healthy subjects without symptoms. Additionally, the study assessed feasibility of prolonged pH monitoring, diagnostic yield based on acid exposure metrics beyond 48 hours of monitoring, and prediction of symptom burden.

METHODS

Adult patients (n=322; 48.5 ± 0.9 years, 61.7% women) with esophageal symptoms with incomplete response to acid-suppressive therapy were prospectively recruited from 2 tertiary care academic centers between November 2013 and September 2017, and evaluated against asymptomatic controls (n=30; 26.9...., 60% women), using symptom questionnaires and 96 hour wireless pH monitoring.96-hour wireless pH monitoring of study patients was compared to data from healthy asymptomatic controls (n=30; 26.9 ± 1.5 years, 60.0% women).

- Acid-suppressive medication were held 7 days prior to the procedure and antacids were allowed for breakthrough symptoms up until the recording periods. Wireless pH capsules were placed 6 cm above the squamocolumnar junction and distal esophageal pH was recorded for up to 4 days; recordings were made after withholding all acid suppressive medication for 7 days.

- AET was calculated for individual days to examine concordance across days. A predominant pattern was defined as greater than or equal to 2 days with the same AET characterization (physiologic = AET < 4%; borderline = 4-6%; pathologic = >6%).

RESULTS

- No adverse events were reported and prolonged recording was well tolerated. Availability of pH data over days for patients and control subjects is provided in the table below.

	Patients (n=322)	Controls (n=30)	P value
Availability of Data (Feasibility of Prolonged Recording)			
At least 1 day	316 (98%)	30 (100%)	1
At least 2 days	312 (96.9%)	30 (100%)	1
At least 3 days	292 (90.7%)	28 (93.3%)	1
4 days	234 (72.7%)	25 (83.3%)	0.21

- As the number of days of recording data increased the number of subjects with a predominant AET pattern increased (p<0.01).

	Patients	Controls
Concordance of Data/Predominant AET Pattern		
2 days	200/312 (64.1%)	22/30 (73%)
≥ 3 days	264/292 (90.4%)	27/28 (96.4%)
4 days	210/234 (89.7%)	24/25 (96.0%)

- Acid Exposure Times (AET) were consistent across recording days and were used to classify patients as physiologic (AET < 4%), pathologic (AET > 6%), or borderline (AET 4-6%).
- When AET was cumulatively averaged across all available study days 52.2% of patients (165/316) had a physiological pattern. 17.1 % of patients (54/316) showed a borderline pattern and 30.7% of patients (97/316) showed a pathologic pattern.
- Patients with a pathologic AET pattern were more likely to report heartburn (p<0.01) and typical reflux symptoms (p=0.001) than patients with a physiologic pattern.
- Baseline GERDQ Score was higher in patients with pathologic AET pattern, based on total average AET (p=0.03) and predominant AET pattern (p=0.02) as compared to patients with a physiologic pattern.

CONCLUSION

Using predominant pattern AET analysis with prolonged pH recording can facilitate the identification of patients who are at risk for reflux symptoms when initial monitoring data are discordant or borderline. Using AET pattern analysis increased the diagnostic yield from 64.1% to 90.4% when 72 hour data was available. Patients with a predominant pathologic AET pattern were more symptomatic, with more typical reflux symptoms compared to patients with a physiologic AET pattern. Prolonged wireless pH monitoring has value in clinical reflux monitoring, to enable assessment of predominant acid exposure patterns and diagnosis.

****THIS CONCLUDES THE CLINICAL SYNOPSIS OF THIS PUBLICATION****

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