

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

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Laura Antoniazzi, Hong T Hua, Christopher G Streets, Nagammapudur S Balaji, Andrea Gattolin, Dimitrios Theodorou, Richard Gurski, Jeffrey A Hagen, Jeffrey H Peters, Cedric G Bremner, Peter F Crookes, Steve R DeMeester, Reginald V Lord, Tom R DeMeester, Dept of Surgery, University of Southern California, Los Angeles, CA

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 th 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.