Clinical Adverse Events Associated with Bravo pH Capsule Monitors: A MAUDE Database Analysis

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BACKGROUND

- The Bravo pH capsule monitoring system is a widely utilized, minimally invasive diagnostic tool.
- Measures acid exposure in the esophagus and transmits data to a receiver to identify and treat patients with gastroesophageal reflux disorder.
- The associated procedural complications are not systematically described in literature.

AIMS

- We aim to investigate post Food and Drug Administration (FDA) approval outcomes associated with the Bravo pH capsule monitor system.

METHODS

- We analyzed post-marketing surveillance data on the Bravo pH capsule from the FDA Manufacturer and User Facility Device Experience (MAUDE) database.
- Individual cases from January 2016 to December 2021 were examined to report device-related injuries and modes of failure.
- This database is an open-access platform that receives device reports from mandatory reporters, including manufacturers and facilities, as well as, voluntarily reporters such as healthcare professionals, patients and consumers.
- These reports allow the FDA to monitor device performance and device-related safety concerns.

RESULTS

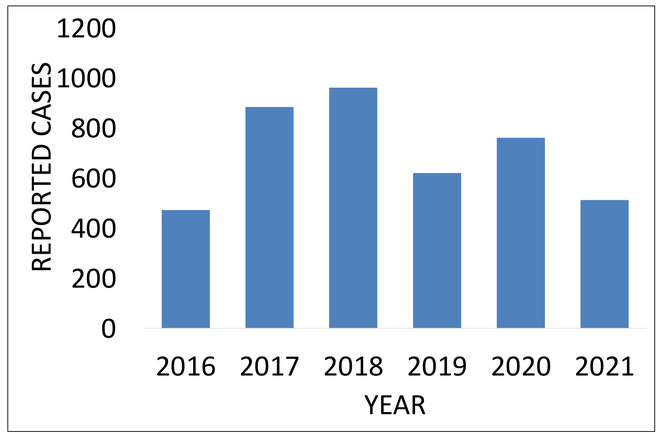

Figure 1. Reported Cases Per Year

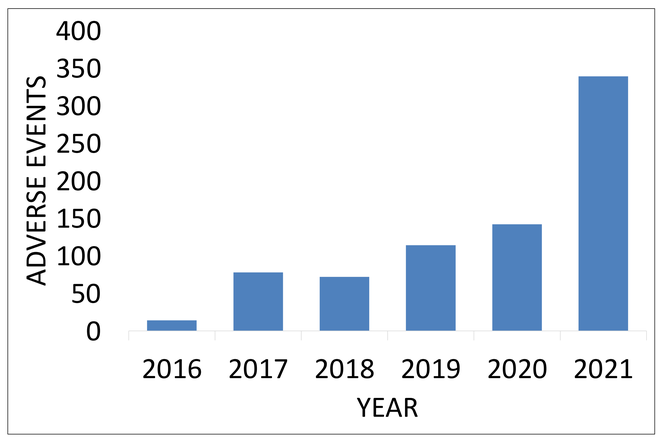

Figure 2. Reported Patient Adverse Events Per Year

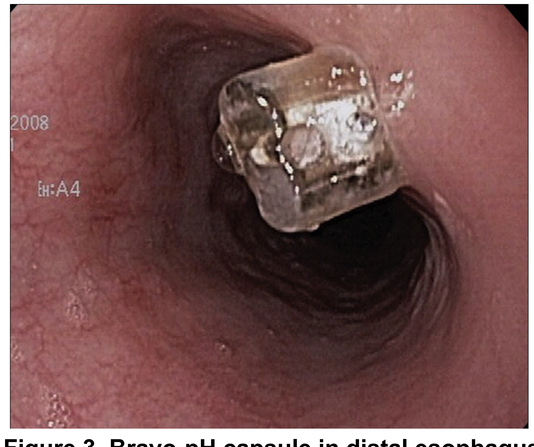

Figure 3. Bravo-pH capsule in distal esophagus
sourced from Agrawal, D., et al. Removal of a Bravo 24-hour pH capsule with endoscopic scissors. *Gastrointestinal endoscopy*, *70*(2), 385–386.

Reported Patient Adverse Events	*n*
Oversedation	26
Pain	53
Chest Pain	40
Ulcer	7
Insufficient Information	50
Vomiting	9
Foreign Body in Patient	107
Airway Obstruction	156
Odynophagia/Dysphagia	7
Unintended Radiation Exposure	69
Aspiration/Inhalation	59
Laceration of Esophagus	22
Perforation of Esophagus	6
Respiratory Insufficiency	1
Asthma	2
Hemorrhage/Blood Loss	16
Sore Throat	6
Cough	2
Fever	2
Discomfort	13
Device Embedded in Tissue	3
Failure of Implant	2
Inflammation	3
Constipation	1
Dyspnea	5
Nausea	4
Tissue Injury/Damage	25
Nasal Obstruction	1
Unspecified Injury	28
Cyanosis	1
Burns	2
Hypoxia	4
Diarrhea	1
Heartburn/Pyrosis	2
Choking	2
Dizziness	2
Foreign Body Sensation in Eye	2
Hernia	1
Sweating	1
Unspecified Infection	1
Neck Pain	1
Tingling	1
Swelling	2
Itching Sensation	1
Cramps	1
Rash	1
Unspecified Reaction	1
Erosion	1

Table 1. Reported Patient Adverse Events

RESULTS

- During the study period, approximately 4210 cases were reported (Figure 1).
- Approximately 4655 device issues and 759 patient complications were examined.
- The most reported device complications were due to loss of or failure to bond (n= 2190, 47.1%), malposition (n= 1074, 23.1%), detachment of the device (n= 325, 7.0%), and communication or transmission problems (n= 270, 5.8%).
- The most reported patient adverse events were airway obstruction (n= 156, 20.6%), followed by foreign body retention (n= 107, 14.1%), unintended radiation exposure (n= 69, 9.1%), aspiration/inhalation (n= 59, 7.8%), and pain (n= 53, 7.0%) (Table 1).
- In this study, there was an increase in reported adverse events per year from 2016 to 2021 (Figure 2).

CONCLUSIONS

- Our analysis revealed a predominance of reported device complications related to capsule adherence and placement difficulties.
- Airway obstruction represented the most commonly reported patient complication.
- An increased in reported adverse events may be related to increased knowledge of the database and reporting requirements.
- This study will help inform the risk/benefit conversation with patients and may facilitate the need to educate on the management of the most critical complications.