Clinical Adverse Events Associated With Esophageal Stents: A MAUDE Database Analysis

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BACKGROUND

- Esophageal stents are widely utilized by Gastroenterologists for the treatment of benign and malignant obstructions.
- A variety of esophageal stent types are currently manufactured, comprised of durable polymers and metal alloys with variable size, diameter and designs.
- Associated procedural complications of esophageal stents are not systematically described in literature.

AIM

- We aim to investigate post Food and Drug Administration (FDA) approval outcomes associated with esophageal stents.

METHODS

- We analyzed post-marketing surveillance data on esophageal stents from the FDA Manufacturer and User Facility Device Experience (MAUDE) database from January 2015 to December 2021.
- 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 and patients.
- Individual reports were analyzed for device-related deaths, injuries and modes of failure.
- These reports allow the FDA to monitor device performance and device-related safety concerns.

RESULTS

Company/Stent Type	Reported Cases	Device Issues	Adverse Events
Boston Scientific Corporation			
Wallflex Esophageal Stent	210	289	90
Ultraflex Esophageal Stent	275	377	25
Agile Esophageal Stent	6	12	2
Polyflex Esophageal Stent	2	2	0
Unspecified implanted device	3	5	4
Taewoong Medical Corporation			
NITI-S Esophageal Covered Stent	144	307	27
NITI-S Esophageal COMVI Stent	12	15	15
Cook Medical Corporation			
Evolution CR Stent, Fully Covered	43	51	21
Evolution CR Stent, Partially Covered	98	138	42
Unspecified implanted device	52	42	51
Olympus Corporation			
Hanarostent TTS	8	9	2
Merit Medical Systems			
Endomaxx Esophageal Stent	30	44	19
Alimaxx-Esophageal Stent	3	3	2
Alveolus Esophageal Stent	1	1	1
Unspecified implanted device	2	4	0
Sewoon Medical Corporation			
Bonastent Esophageal Reduced Stent	9	13	2

Table 1. Reported Device Problems and Adverse Events, Categorized by Device Type

Reported Adverse Events	*n*
Dysphagia/Odynophagia	29
Discomfort	7
Erosion	17
Pneumonia	6
Perforation	17
Fistula	12
Dyspnea	2
Airway Obstruction	1
Hemorrhage/Bleeding	22
Nausea	4
Peritonitis	3
Fever	5
Obstruction/Occlusion	22
Failure to Implant	7
No code available	32
Vomiting	8
Pain	16
Blood Loss	8
Difficulty Chewing	2
Chest Pain	6
Foreign Body in Patient	9
Cardiac Arrest	2
Adhesion	2
Ulceration	2
Death	24

Table 2. Reported Patient Adverse Events

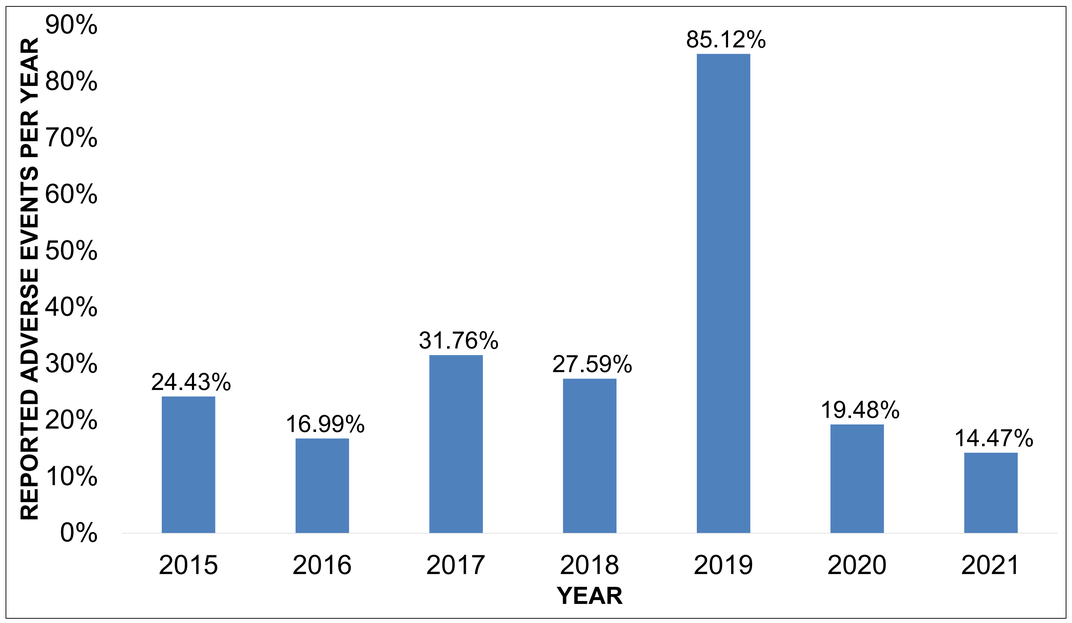

Figure 1. Reported Patient Adverse Events Per Year

RESULTS

- During the study period, approximately 899 reported cases with 1312 device issues and 303 patient complications were examined (Table 1).
- The most reported device issues were due to activation, position, or separation failure (n= 597, 45.5%), migration or expulsion of device (n=120, 9.1%), and break (n= 96, 7.3%).
- A number of reports described an unclassified device issue without specifying device or operator problem (n=100, 7.6 %).
- The most reported patient adverse events were dysphagia or odynophagia (n = 29, 9.6%), followed by death (n = 24, 7.9%), hemorrhage (n = 22, 7.3%), and obstruction or occlusion (n = 22, 7.3%) (Table 2).
- A number of cases described unspecified patient adverse events (n= 32, 10.6%).
- In this study, the most reported adverse events occurred in 2019 (Figure 1).

CONCLUSIONS

- Our analysis revealed a predominance of reported device complications related to activation, position, and separation difficulties.
- Dysphagia or odynophagia represented the most commonly reported patient complication.
- This study will help inform the risk/benefit conversation with patients and may lead to a more detailed approach on how to mitigate and manage complications.
- This study highlights areas of difficulty for clinicians in order to identify steps to bypass the most common failure points.