Analysis Of Reported Adverse Events Related to Over the Scope Clips: A MAUDE Database Analysis

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Background

- Over-the-scope clips have been increasingly used in the management of bleeding, perforations, fistulae, and anastomotic leaks in the gastrointestinal tract
- Our study aims to report and analyze adverse events and device failures associated with over the scope clip systems using the FDA's Manufacturer and User Facility Device Experience (MAUDE) database

Aims and Methods

- We analyzed the post-marketing surveillance data from the FDA MAUDE database of the two over-the-scope clip systems available in the United States: The Padlock clip system ® and the Ovesco ® over-the-scope clip systems from January 2013 through May 2022

Tables

Device-related problems	Number
Failure of device activation	13
Other	8
Protrusion or extrusion of over the scope clip system	7
Failure of positioning of the device	5
Separation problem	3
Detachment of the device	2
Defective device component	2
Total	40

Tables

Adverse events in patients	Number
Esophageal laceration	4
Perforation	4
Bleeding	3
Colonic stenosis	2
Local trauma	1
Pain	1
Gastro-gastric fistula	1
Pyloric stenosis	1
Recurrent abscess	1
Damage to colonic tissue	1
Ulcer at the stomach and pylorus junction	1
Total	20

Results

- Forty medical device reporting claims were found from January 2013 through May 2022
- Adverse events were classified as device-related problems and patient-related adverse events
- Forty device-related problems were reported, along with twenty device-related adverse events
- Most device-related problems were reported in the Padlock defect closure system ® (n=23), followed by the Padlock pro clip system ® (n=8) and Ovesco ® OTSC clip system (n=9)
- The most common device-related problem was related to the failure of deployment of OTSC (n=13), followed by material protrusion or extrusion (n=7)
- The most common patient adverse events were perforation (n=4), esophageal laceration (n=4), bleeding (n=3), and luminal stenosis (n=3).

Conclusion

- Using the data from a publicly available database, we reported device- and patient- related adverse events that are associated with the use of Padlock clip ® and the Ovesco ® over-the-scope clip systems
- Failure of OTSC deployment and perforation were the most common device-related problem and patient-related adverse events, respectively
- The identification of common adverse events has the potential to optimize device design and patient outcomes
- It is important for the endoscopists to be mindful of the common as well as rare adverse events associated with over-the-scope clip systems