Analysis of Reported Adverse Events Related to Hemospray: A MAUDE Database Analysis

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Introduction

- Topical hemostatic powder is a highly absorptive powder that forms an adherent mechanical barrier and coagulates active bleeding in the gastrointestinal tract.
- It is the only hemostatic powder which has been approved by the FDA in the United States.
- Since its approval in May 2018, Hemospray has been increasingly used to manage upper and lower GI bleeding.
- Data on adverse events are lacking.
- We aim to report and analyze adverse events associated with Hemospray using the FDA’s Manufacturer and User Facility Device Experience (MAUDE) database.

Methods

- We analyzed the post-marketing surveillance data from the FDA MAUDE database for Hemospray, initially known as TC-325 from June 2018 through April 2022.

Results

- 490 medical device reporting claims were identified from June 2018 through April 2022. Two duplicated were identified, so 488 claims were analyzed.
- There were 475 device-related problems, eleven patient-related adverse events, and two adverse events in healthcare staff members.
- The most common device-related problems were activation failure or failure to fire (n=373, 78.5%), obstruction of carbon dioxide (CO2) flow (n=42, 8.8%), inability to remove the Hemospray from the endoscope (n=18, 3.8%), device fracture (n=10, 2.1%), CO2 leak (n=9, 1.9%), defective Hemospray device (n=5, 1.1%) and explosion (n=2, 0.42%). 180 out of these 475 device-related problems were reported on the same adverse event claim.
- The most common combination claim was activation failure or failure to fire and obstruction of CO2 flow. Patient-related adverse events included perforation (n=5), unspecified tissue injury or bleeding (n=3), allergic reaction (n=1), and infection (cholangitis) from the use of Hemospray in the bile duct (n=1).
- Two events reported chest pain tightness in healthcare staff after inhaling Hemospray particles.

Discussion

- While Hemospray is a useful tool in the armamentarium for endoscopists in the management of gastrointestinal bleeding, it is important for endoscopists to be mindful of these adverse effects.

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