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

Khalid Ahmed, MD[1]; Mohamed Adballah, MD[2]; Daniyal Abbas, MD[3]; Abubaker Abdalla, MD[4]; Gaurav Suryawanshi, MD[2]; Nicholas McDonald, MD[2] ; Shifa Umar, MD[5]; Nicholas McDonald, MD[2]; Mouhand F. Mohamed, MD[2] ; Brian Hanson, MD[2,6]; Mohammad Bilal, MD[2,6]

1. The Wright Center for Graduate Medical Education, Scranton, PA 2.University of Minnesota, Minneapolis, MN, 3.East Carolina University, Greenville, NC. 4Emory University, Atlanta, GA, 5. Mayo Clinic, Rochester, MN. 6.Minneapolis VA Medical Center, Minneapolis, MN.

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

Figure 1: Hemospray Endoscopic Hemostat Device manufactured by COOK Medical
Image source: https://gutsandgrowth.com/tag/hemospray/

This project is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of awards totaling $17,038,990 with 63% percent financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov.