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Name of Journal: *World Journal of Gastrointestinal Endoscopy*

Manuscript NO: 88799

Manuscript Type: ORIGINAL ARTICLE

Observational Study

Adverse events associated with the Gold Probe and the Injection Gold Probe devices used for endoscopic hemostasis: A MAUDE database analysis.

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Abstract

BACKGROUND

Gastrointestinal (GI) bleeding accounts for over half a million admissions annually and is the most common GI diagnosis requiring hospitalization in the United States. Bipolar electrocoagulation devices are used for the management of gastrointestinal bleeding. There is no data on device-related adverse events for Gold Probe and Injection Gold Probe.

AIM

We aimed to analyze this using ³ the Food and Drug Administration (FDA's) Manufacturer and User Facility Device Experience (MAUDE) database from 2013 to 2023.

METHODS

We examined post-marketing surveillance data on GP and IGP from the FDA MAUDE database to report device-related and patient-related adverse events between 2013-2023. The MAUDE database is a publicly available resource providing over 4 million records relating to medical device safety. Statistical analyses were performed using IBM SPSS Statistics V.27.0 (IBM Corp., Armonk, NY).

RESULTS

Our search elicited 140 reports for Gold Probe and 202 reports for Injection Gold Probe, respectively, during the study period from January 2013 to August 2023. Malfunctions reportedly occurred in 130 cases for GP, and actual patient injury or event occurred in 10 patients. A total of 149 patients (74%) reported with Injection Gold Probe events suffered no significant consequences due to the device failure, but 53 patients (26%) were affected by an event.

CONCLUSION

Gold probes and Injection Gold probes are critical in managing gastrointestinal bleeding. This study of the FDA MAUDE database revealed the type, number, and trends of reported device-related adverse events. The endoscopist and support staff must be aware of these device-related events and be equipped to manage them if they occur.

INTRODUCTION

Gastrointestinal (GI) bleeding accounts for over half a million admissions annually and is the most common GI diagnosis requiring hospitalization in the United States(1). Lesions with high-risk stigmata, which are associated with high rates of recurrent bleeding (50% to 80%) and result in significant morbidity if treated with medical therapy alone. Thus, the latest American College of Gastroenterology (ACG) guidelines recommend endoscopic therapy for ulcers with active spurting or oozing and nonbleeding visible vessels. The management of nonvariceal upper GI bleed (UGIB) has evolved tremendously with the advent of therapeutic endoscopic hemostasis devices and techniques. Studies have shown that thermal contact devices such as bipolar electrocoagulation and heater probes decrease the incidence of re-bleeding compared with no endoscopic therapy (2)

Overall, devices used to achieve hemostasis using thermal therapy were safe. The serious adverse events associated with these devices include uncontrollable bleeding and perforation.⁽³⁾ Pooled data showed that the rate of bleeding that required urgent surgery was 0.3%, and perforation was 0.5%. ⁽⁴⁾

The Gold Probe (GP) and Injection Gold Probe (IGP) (Boston Scientific Corp., Natick, Mass.) are two commonly used devices to achieve endoscopic hemostasis. IGP can deliver an injection as well as thermal therapy. No data on device-related adverse events for these devices used routinely to achieve endoscopic hemostasis is available.

Thus, we aimed to evaluate the events associated with using Gold Probe and Injection Gold Probe using ³ the Food and Drug Administration (FDA's) Manufacturer and User Facility Device Experience (MAUDE) database from 2013 to 2023.

MATERIALS AND METHODS

We examined post-marketing surveillance data on GP and IGP from the FDA MAUDE database to report device-related and patient-related adverse events. The MAUDE database is a publicly available resource providing over 4 million records relating to medical device safety. The MAUDE database has medical device reports (MDRs) submitted to the FDA by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters such as healthcare

professionals, patients and consumers(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm#fn1>).

It consists of four primary (Master Event, Device, Patient, Text) and two supplemental (Device Problems and Problem Code Descriptions) file types, which, when combined, provide a detailed account of an adverse event or product problem report. Healthcare professionals have used MAUDE to review events associated with specific products or procedures. Several articles referencing MAUDE have been published analyzing adverse events specific to a particular outcome, product, or body system. It is publicly

available online and de-identified. Therefore, no institutional review board approval was required for this study.

OUTCOMES AND STATISTICAL ANALYSIS:

We queried the MAUDE database from January 2013 to August 2023. The MAUDE web search feature is limited to adverse event reports within the past ten years. The data was analyzed for device issues and patient adverse events. The primary outcome measure of this study was the failure modes of the endoscopic diathermy *Gold Probe™* (Boston Scientific) and injection diathermy *Injection Gold Probe™* (Boston Scientific). Secondary outcomes included significant complications associated with device failure. The MAUDE database cannot capture the utilization of *Injection Gold Probes* in the United States; therefore, the actual incidence rate of each failure or complication type cannot be assessed. Categorical variables were presented as numbers; all statistical analyses were performed using IBM SPSS Statistics V.27.0 (IBM Corp., Armonk, NY).

RESULTS

Our search elicited 140 reports for *Gold Probe* and 202 reports for *Injection Gold Probe*, respectively, during the study period from January 2013 to August 2023. The procedure type for *Gold Probe* use was esophagogastroduodenoscopy (47) followed by colonoscopy (25), bronchoscopy (7), Endoscopic Retrograde Cholangiopancreatography (ERCP) (6), enteroscopy (3), missing procedure information (52), *Table 1*. The procedure types for *Injection Gold Probe* were esophagogastroduodenoscopy (174) followed by colonoscopy (16), ERCP (11), and enteroscopy (1), *Tables 2*.

Primary outcomes outlining failure modes for the *Gold Probe* and *injection Gold Probe* is outlined in *Table 3 and 4*. *Gold Probe* failure modes were failure to deliver energy (107), followed by material separation or fracture of the probe tip (28), arcing (1), missing component (1), bent tip (1), and detachment of device (2). *Injection Gold Probe* failure

modes were failure to deliver energy (115), followed by material separation or fracture of the probe tip (34), crack (9), device detachment (27), material puncture (5), and mechanical problems (12).

Malfunctions reportedly occurred in 130 cases for *GP*, and actual patient injury or event occurred in 10 patients. In assessing secondary outcomes, no deaths were reported, although two patients experienced prolonged hemorrhage and two fiberoptic endoscopes were damaged by the device; 7 patients required a secondary procedure to retrieve the detached probe. Most patients with a reported *Gold Probe* event suffered no significant consequences due to the device failure (93%), but 7% required a second procedure or experienced prolonged stay or discomfort, **Table 5**. Most patients reported with Injection *Gold Probe* events (74%) suffered no significant consequences due to the device failure, but 26% of patients were affected by an event (prolonged hemorrhage, need for a secondary procedure due to a detached probe), **Table 6**. Reports by year decreased significantly after 2017 for both Gold Probe and Injection Gold Probe, **Table 7**.

DISCUSSION

Our study comprehensively analyzes events reported with GP and IGP from 2013 to 2023. For both GP and IGP, the most reported problem is the "failure to deliver energy." Investigating the root cause of this recurrent issue with these devices is imperative. If user error is identified as a significant factor, offering additional training to the healthcare professionals using these devices and refining the user guidelines would be beneficial.

The significantly higher number of reported events with IGP devices than with GP devices is noteworthy. While a higher usage frequency might contribute to the increased reporting, the pronounced rate of patient-related adverse events stemming from IGP failures cannot be dismissed lightly. Especially concerning are instances

requiring repeat procedures, as they amplify the risk profile for patients and accentuate the resource burdens on healthcare institutions.

The manufacturer for the GP and IGP reports patient-related adverse events, including perforation, bleeding, aspiration pneumonia, and septicemia/infection, and reports a potential electrical hazard to the patient and operator with possible adverse including fulguration, burns, stimulation, and cardiac arrhythmia(5). However, there have been no studies so far that have looked at the device-related events that could occur with GP and IGP. Our study is the first to analyze the device-related events reported. It sheds light on device-related complications, thus enhancing the existing knowledge pool crucial for daily clinical applications. Data regarding other bipolar devices was sparse and thus a comparative analysis could not be done.

The 2021 ACG guidelines for managing UGIB strongly ⁵ recommend endoscopic hemostatic therapy with bipolar electrocoagulation, heater probe, or injection of absolute ethanol for patients with UGIB due to ulcers. Several studies have proven the efficacy and overall safety of GP and IGP to manage gastrointestinal hemorrhage(2, 6, 7). The safety and efficacy of bipolar devices have been also established while managing lower GI bleeding(8, 9). GP and IGP are Bipolar devices used to manage GI bleeding during endoscopy. Given the ubiquity of these bipolar devices in clinical scenarios, endoscopists, and auxiliary staff must be apprised of potential device-related pitfalls.

Interestingly, the findings of this study also suggest that there was a decline in the events for both IGP and GP from 2017. Endoscopists familiarity with the device and adequate training in its usage, and manufacturer's improvement of the quality of the device could have led to fewer events. Usage of other hemostatic devices could have also contributed to this. Over-the-Scope Clips (OTSC) has been shown to be as effective as standard therapy in non-variceal upper gastrointestinal bleeding since 2017(10). OTSC has also proven effective in large ulcers up to 5cm(11), with a high success rate of

hemostasis (80%) even in recurrent bleeding and has also competed with GP and IGP as first line hemostatic method since 2017(12).

At around the same time, hemostatic aerosolized powders such as TC 325 (Hemospray[®]) have become part of the hemostatic armamentarium available to the endoscopist, especially effective in the setting of diffuse mucosal bleeding (13, 14).

These newer hemostatic technologies may have contributed to a decline in use of IGP and GP since 2017. It's also conceivable that the manufacturing process may have effectively addressed the prior device failure reports to redesign and improve quality control hence leading to a decline in the device malfunction/ failure reports since 2017.

Guidelines for non-variceal upper gastrointestinal bleeding have emphasized that epinephrine injection needs to be combined with a secondary hemostatic modality and hence IGP use may have increased over GP use. IGP conveniently uses both injection and thermocoagulation sequentially without interruption to introduce another hemostatic method endoscopically. This may have contributed to increase in IGP use over GP and consequently higher device malfunction reports(15).

This study has limitations. ¹ The MAUDE web search feature is limited to adverse event reports within the past ten years. ¹ This passive surveillance system has its limitations. There is a potential for submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to under-reporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about the frequency of the device use.

CONCLUSION

Gold probes and Injection Gold probes are critical in managing gastrointestinal bleeding. This study² of the FDA MAUDE database revealed the type, number, and trends of reported device-related adverse events. The endoscopist and support staff must be aware of these device-related events and be equipped to manage them if they occur.

ARTICLE HIGHLIGHTS

Research motivation

GP and IGP are vital in managing gastrointestinal bleeding, yet they present notable risks. Awareness of these risks is essential for endoscopists and support staff. The study highlights the need for improved device safety and better management strategies in case of device failure.

Research objectives

The analysis revealed 140 reports for GP and 202 reports for IGP, with the majority of device failures being attributed to the failure to deliver energy. While most events did not lead to significant patient consequences, a notable proportion (26% for IGP) resulted in adverse outcomes like prolonged hemorrhage or the need for secondary procedures.

Research methods

The study utilized post-marketing surveillance data from the FDA's MAUDE database, analyzing reports for GP and IGP from January 2013 to August 2023. Statistical analyses were performed using IBM SPSS Statistics V.27.0 to identify primary and secondary outcome measures.

Research results

The primary objective is to evaluate the events associated with the use of GP and IGP, specifically focusing on the types and frequencies of device failures and their impact on patient outcomes.

Research conclusions

The motivation for this research stems from the lack of comprehensive data on device-related adverse events for GP and IGP, devices commonly used in managing gastrointestinal bleeding, despite their widespread clinical use.

Research perspectives

This study investigates the device-related adverse events associated with the use of Gold Probe (GP) and Injection Gold Probe (IGP) in endoscopic hemostasis, leveraging data from the FDA's Manufacturer and User Facility Device Experience (MAUDE) database over a decade (2013-2023).

Research background

The findings underscore the need for ongoing surveillance, device improvement, and consideration of emerging hemostatic technologies. Further research into device design and usage guidelines could enhance safety and efficacy in clinical practice.

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