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Abstract Discussion Forum **(0)**

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DEVICE MALFUNCTIONS WITH USE OF FULL THICKNESS RESECTION DEVICES: ANALYSIS OF THE MAUDE DATABASE

Society: ASGE

Track: Technologies and Procedural Innovation

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Introduction

Full thickness resection device (FTRD) is a dedicated device for endoscopic full thickness resection. It comprises an assembly of a transparent cap, over the scope clip, graspers and snare. Recent literature supports its efficacy and safety for full thickness resections; however, the real-world experience of using these devices is limited. In this study, we explored the manufacturer and user device experience (MAUDE) database maintained by the US food and drug administration (FDA) to explore the adverse events reported with FTRD.

Methods

The open access MAUDE database was evaluated from June 2018 to September 2024 for all device-related adverse events. The manufacturer and the device brand name (Full Thickness Resection Device) were used as keywords for the search. The adverse events were manually reviewed for events involving the device, patient related complications or both. All the adverse events were graded based on the adverse events in gastrointestinal endoscopy (AGREE) classification.

Results:

There were 29 reported issues with the FTRD. 18 (62.1%) were with the colonic FTRD device, 8 (27.5%) were with diagnostic FTRD and remaining were related to gastroduodenal FTRD.

There were 25 cases of clip misdeployment. In 16 (64%) cases, the clip deployment was not visually confirmed prior to resection. In the remaining 9 (36%) reports, the clip did not deploy despite a few attempts. In two cases of gastric full thickness resection, the clips fell off the resection site on the second and tenth post-resection days respectively resulting in gastric perforations. In another case, the snare slipped out of the resection cap resulting in colonic perforation. This was closed with hemostatic clips endoscopically and no surgical intervention was required. Finally in one case the grasper did not deploy well leading to perforation in the cecum around the appendiceal orifice.

Overall, 26 cases developed bowel perforation due to the adverse event. The most common site of perforation was the cecum (n= 13; 50%) followed by the sigmoid colon (n = 3; 11.5%). A total of 21(72.4%) patients' adverse events required surgical intervention (AGREE classification: Grade IIIb).

Among the cases reported, there was one instance of mortality after duodenal perforation. The patient required surgery and a prolonged hospitalization due to the adverse event but could not survive due to prior existing comorbidities.

Conclusion:

There are very few reported adverse events with the FTRD over the last 6 years however, device malfunctions with the FTRD device contributed to serious adverse events requiring surgical interventions. Most malfunctions werre related to clip deployment. This information could guide design improvements and training programmes for these devices. Also, these concerns should be discussed with the patients as a part of the informed consent process.

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Dr. Achintya Singh

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