CLINICAL ENDOSCOPY

Could a bleeding-sensor device be established as a new paradigm for detecting upper gastrointestinal bleeding before performing endoscopy?

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See "Novel upper gastrointestinal bleeding sensor capsule: a first human feasibility and safety trial" by Lukas Bajer, Marvin Ryou, Christopher C. Thompson, et al., Clin Endosc 2024;57:203–208.

The trend of upper gastrointestinal bleeding (UGIB) has been on a gradual decline recently.[1-3] However, UGIB remains a frequent symptom that prompts visits to the emergency room. Advancements in endoscopic hemostatic procedures, use of proton pump inhibitors, and eradication therapy of *Helicobacter pylori* infection have considerably improved the treatment of UGIB.[4,5] However, consensus is still lacking on the methods or measures that determine the appropriate level of intervention and treatment in the emergency room. Prior scoring systems that predict the severity of UGIB have not demonstrated sufficient reliability across various studies, casting doubt on their clinical application.[6-8] Due to these reasons, the initial management approaches for patients presenting with UGIB are not always consistent. The inconsistency raises the risk of overlooking patients who require treatment, conversely, managing patients excessively or performing unnecessary interventions. Such practices can lead to wastage of medical resources and hinder the appropriate treatment of other patients with critical illnesses.

In this issue of *Clinical Endoscopy*, Bajer et al.[9] conducted the first human feasibility and safety trial on a device known as PillSense system (EnteraSense Ltd.). This device is easy to use and can detect real-time bleeding noninvasively. It is shaped as a swallowable capsule and is equipped with an optical sensor that detects blood material.[10] Although the number of patients tested was small (only 10), the device successfully detected the presence of blood in all cases. In one patient, a positive result regarding blood presence was demonstrated even without a direct administration of blood material, indicating a high expectation of sensitivity for this device. Unlike the previously proposed UGIB prediction systems based on clinical or laboratory findings, the PillSense system provides real-time detection of blood material within the gastrointestinal tract, thus making it highly attractive. However, essential issues must be addressed before the clinical implementation of this device.

A primarily important issue is determining whether the presence of blood could be considered as an indication for emergent intervention or hospitalization. In cases where bleeding stops or is relatively mild, as seen in various types of gastritis, treatment with medication alone at an outpatient clinic may be sufficient. Establishing criteria to differentiate between mild bleeding that does not require hospitalization or interventions and severe bleeding requiring prompt intervention or hospitalization would be a critical factor in emergency department. The

authors also noted that this study primarily focused on feasibility and safety, leading to limitations in assessing the amount and rate of bleeding. However, for the above-mentioned system to develop into one that enables us to determine the necessity of emergent management, various measurements, including bleeding volume and speed, as well as the correlation analysis with reliable clinical variables, have to be considered.

Second, the distinction between "existing" bleeding and "ongoing" bleeding will be crucial. Ongoing bleeding can directly warrant emergent endoscopic procedures. The PillSense system does not appear to possess this capability as of now. Differentiating between these two conditions would substantially enhance its value for clinical application in future studies.

Third, predicting the location of bleeding poses another challenge. When the capsule is swallowed, it briefly passes the esophagus and primarily stays in the stomach. However, the transit time from the stomach to the duodenum varies among individuals, which poses a technical challenge in confirming the presence of duodenal bleeding. Considering that duodenal bleeding also requires treatment through endoscopy, addressing this issue is important. Determining the duration when the capsule reaches the duodenum and establishing methods to track its location are essential for identifying the bleeding site, particularly for duodenal bleeding. This concern also raises the question of the optimal duration for conducting the measurements.

The last concern pertains to safety. Although no cases were reported in this study, the possibility of retention in the small bowel still exists. The use of this system might be restricted in patients with prior gastrointestinal surgeries or strictures.[11,12]

In summary, the system for real-time blood detection proposed in this study emerges as an appealing method for confirming the presence of UGIB compared to existing prediction systems. Although it is currently in the very early stages of development, technological improvements are expected, rendering it a valuable device for future clinical applications.

Conflicts of Interest

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