

Ingestible sensor capsule with extended battery capacity allows early diagnosis of GI malignancy in comorbid patients with occult bleeding and anemia ▶

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ABSTRACT

HemoPill is a commercially available ingestible electronic capsule that detects hematin and blood through photometric measurements. An examination with HemoPill requires no special preparation and can be done bedside. Its major advantage is noninvasive luminal blood detection, requiring only a small amount of blood or hematin (> 20 mL) for a positive result, making it especially suitable in multimorbid and/or geriatric patients not primarily fit for endoscopic diagnostic allowing rapid and uncomplicated bleeding detection.

Recent clinical reports showed that HemoPill is useful in stratifying patients with anemia and bleeding in the setting of an Emergency Department. The second generation with an extended battery capacity of 9 hours opens the possibility of detecting blood in the middle and lower gastrointestinal tract.

Herein we report another advantage of the extended battery capacity allowing noninvasive bleeding detection in the middle and lower gastrointestinal tract, leading to early endoscopic diagnosis of gastrointestinal malignancies with occult bleeding in comorbid patients with severe anemia.

Introduction

HemoPill is a swallowable electronic capsule (▶ Fig. 1a) that detects hematin and blood through photometric measurements, which are wirelessly transmitted every 4 seconds to a proprietary receiver (▶ Fig. 1b) that is put in a single-use bag worn by the patient during the examination. The photometric measure-

ments are plotted over time and displayed as the “HemoPill Indicator” (HI) with a HI reaching the red marked zone on the receiver display indicating detection of intraluminal blood or hematin (▶ Fig. 1b and ▶ Fig. 2a). Preclinical studies showed that it diagnoses bleeding in the gastric lumen with high sensitivity and specificity [1], with measurements being robust to the effects of gastric content [1, 2]. Aside from intact deglutition, ex-



► **Fig. 1** a The swallowable bleeding sensor capsule, HemoPill, measures 26.3 mm x 7 mm with a measuring gap for photometric measurements. b Proprietary HemoPill receiver, which plots the photometric measurement results over time. This figure displays an example of a positive blood detection, showed by a HI within the red zone. Source: Ovesco Endoscopy AG, Tübingen, Germany

amination with HemoPill requires no special preparations other than a glass of water and can be done bedside. Its major advantage is noninvasive luminal blood detection in multimorbid and/or geriatric patients not primarily fit for endoscopic diagnostic, allowing rapid and uncomplicated bleeding detection. It has been commercially available in Germany since 2019.

Recent clinical reports have shown that it is useful for stratifying patients with anemia and bleeding in the setting of an Emergency Department [3]. This study utilized the first capsule generation with a battery capacity of 2 to 3 hours, allowing blood detection only in the upper gastrointestinal tract. A recent update brought an increased battery capacity of 9 hours, opening the possibility of detecting blood in the middle and lower gastrointestinal tract, as shown by Brunk et al [4].

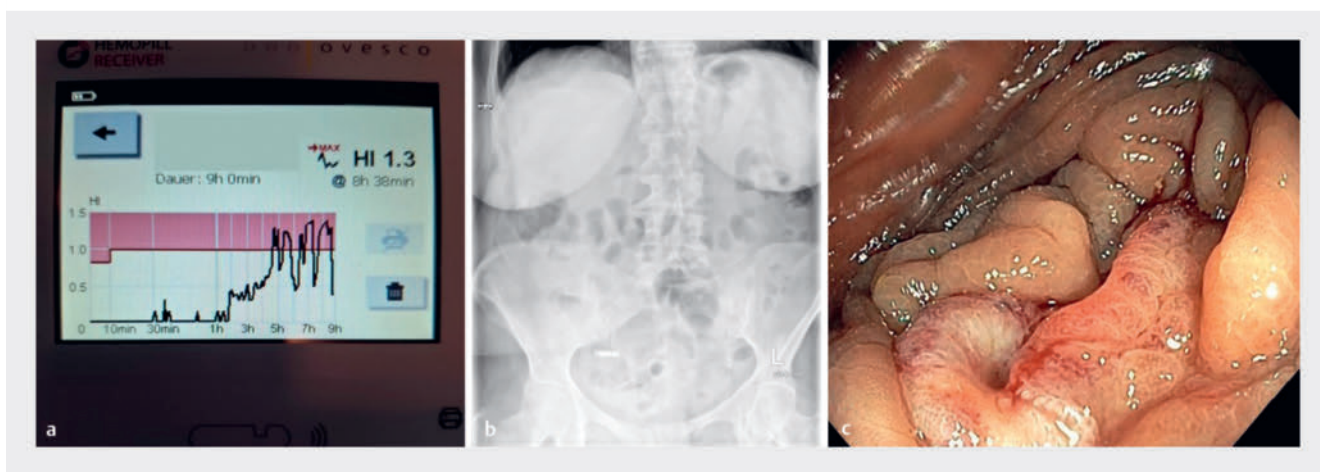
Herein we report another advantage of the extended battery capacity allowing noninvasive bleeding detection in the middle and lower gastrointestinal tract, leading to early and ex-

pedited endoscopic diagnosis of gastrointestinal malignancies in two patients with chronic bleeding leading to severe anemia.

First case

A 56-year-old female patient was referred due to recurrent anemia and melena with a hemoglobin (Hb) concentration of 5 g/dL. A month before presenting to our unit, she had been admitted to another hospital, also due to severe anemia with a Hb of 3 g/dL. There, a colonoscopy was performed and revealed no sign of bleeding but a sigmoid tubular adenoma, which was thought to be the potential bleeding source and thus resected without complication. After transfusion of 3 units of packed red blood cells (pRBCs), she was discharged with stable Hb and no further signs of bleeding. An upper gastrointestinal study (esophagogastroduodenoscopy [EGD]) was not performed for unknown reasons. The patient's medication was notable for apixaban as stroke prophylaxis due to atrial fibrillation.

In our unit, an EGD was performed after transfusing 2 units of pRBCs, revealing no intraluminal blood or other bleeding sign. The patient was scheduled for a repeat colonoscopy followed by standard capsule endoscopy but she did not tolerate bowel preparation due to nausea and recurrent vomiting. Thus, only sigmoidoscopy after an enema was performed, which revealed no signs of bleeding or abnormality at the site of the previous polypectomy. At that point, no further clinical signs of bleeding or melena occurred and the Hb remained stable. The patient remained in the hospital for observation, during which she suffered a syncope due to profuse melena. An urgent EGD again revealed no blood or bleeding in the upper gastrointestinal tract. Because the previous bowel preparation had not been tolerated and was deemed impossible after syncope, HemoPill was utilized and placed directly into the duodenum using a snare during the urgent EGD. After 1 hour, the receiver indicated a positive signal (► **Video 1**). Because the receiver has no position indicator or other geographical function, a plain abdominal x-ray was taken shortly afterwards to approximate the



► **Fig. 2** a Positive HI indicating that blood has been detected 5 hours after swallowing the capsule with a maximum HI reached after 8 hours. b Plain abdominal X-ray shortly after the positive HI. The Hemopill was approximately located in projection of the cecum. c Colonoscopy revealed a nontraversable stenosis, proven to be cancer in the histology. Source: Ovesco Endoscopy AG, Tübingen, Germany

VIDEO



► **Video 1** The video shows direct placement of the capsule into the duodenum during the urgent EGD to expedite the diagnostic pathway and bypass the gastric passage. After approximately 1 hour, the HI was positive indicating positive blood detection. Soon after, a plain abdominal x-ray was performed showing the capsule to be approximately at the level of the ligament of Treitz. Urgent push enteroscopy revealed a bleeding tumor in the jejunum, histologically confirmed as an angiosarcoma.

location of the capsule, and thus, the source of bleeding. It was identified to be in the proximity of the Treitz ligament, suggesting bleeding in the proximal jejunum. Urgent push enteroscopy was performed and revealed a sponge-like dark solid lesion with a large blood clot and active diffuse bleeding upon contact approximately 90 cm from the incisors. The lesion was tattooed and hemoclips were placed for markings. Urgent computed tomography (CT) failed to identify the tumor in the jejunum and only the clips were seen. A surgical consultation was requested and jejunum resection was performed. Intraoperatively a tumor was confirmed, which the pathology showed to be an angiosarcoma ().

Second case

A 77-year-old female patient was referred due to severe anemia with a Hb of 5 g/dL without any clinical sign of bleeding. Due to obesity with a body mass index of 37 kg/m² and her advanced age, we opted to postpone endoscopic diagnosis and utilized HemoPill after first transfusing 2 pRBCs. After approximately 5 hours, a positive signal was recorded (► **Fig. 2a**). A plain abdominal x-ray shortly afterward revealed the capsule to be in the projection of the cecum. Consequently, the patient was scheduled for a timely colonoscopy and bowel preparation was initiated (► **Fig. 2b**). Colonoscopy showed stenosis in the ascending colon (► **Fig. 2c**), which proved to be malignant on histology and a malignant polyp in the sigmoid, which was resected curatively during a second colonoscopy. No further tumor manifestation was seen during the patient's staging, allowing her to proceed to surgery, which confirmed the diagnosis of colon carcinoma.

Discussion

These two cases showcased HemoPill's potential as a useful novel adjunct in our arsenal of noninvasive bleeding diagnostic tool in the upper, middle, and lower gastrointestinal tract. Because of its ease of use, not requiring any preparation other than intact swallowing and a glass of water, it is very appropriate for use in geriatric or comorbid patients for whom endoscopic examinations are not suitable. In patients without intact swallowing and without any signs of bleeding on EGD, HemoPill can be placed directly in the duodenum, allowing rapid blood detection in the middle and lower gastrointestinal tract without the necessity for bowel preparation. In contrast to a radiological study, such as CT or magnetic resonance imaging (MRI), it is immediately available and requires no contrast agent, which is beneficial in patients with chronic kidney failure. Because of its small size (approximately half the thickness of a standard capsule endoscopy), the chance of capsule retention is significantly reduced.

A major drawback of HemoPill compared with contrast-enhanced CT angiography, is lack of exact bleeding localization. Furthermore, photometric results are only sent to a local receiver within a limited range of 50 cm, which requires that the patient wear the receiver during the examination. Thus, multiple manual checks are needed to see if results turn positive and to schedule a timely plain abdomen study, which is currently necessary to estimate the location of the HemoPill (and hence, the bleeding). In our cases, the plain abdomen studies were taken approximately 30 to 60 minutes after the positive result. Had they been taken at a later time, it may have been more difficult to identify the site of the hemorrhage. Nevertheless, the x-ray results would still have been helpful, because the "hemorrhage search area" would be narrowed down to the capsule site and the area proximal thereof. Performing a CT scan is an alternative to a plain abdomen study, which could provide the exact capsule location but can be logistically challenging in a lot of units due to acute availability, especially on weekends and night. Furthermore, patients would also experience greater radiation exposure. In the first patient, the actively bleeding tumor was not visible on the urgent CT scan, despite the use of contrast agent.

The multiple manual checks represent an enormous challenge for staff, especially if a patient is not able to check the result independently. In our experience, these challenges can only be tackled when the nursing staff is highly motivated, the patient and family are empowered to understand the importance of multiple receiver checks during the 9-hour study period, and abdominal imaging is performed timely to estimate capsule location and with it, the bleeding source. Future technical improvements are needed to improve and facilitate capsule localization. A longer transmitting distance to the receiver or another alerting system for the nursing staff in case of a positive HI could also improve practicality, avoiding the need for multiple direct checks by patients.

Compared with conventional pan-enteric video capsule endoscopy (PCE), the HemoPill is smaller at 7 × 26.3 mm (vs. PillCam Colon or Pillcam Crohn at 11.6 × 31.5 mm), offering a

more comfortable swallowing experience and theoretically reduced risk of capsule retention. The biggest disadvantage of the device is that it cannot offer any image from the gastrointestinal tract, but it is also more practical, because it requires no fasting or bowel preparation. Although results from PCE can be unreliable if the view is obscured by bowel contents, HemoPill measurements are principally unaffected by recent meals or other intestinal or gastric content. In addition, PCE recordings are typically reviewed a day after the capsule is swallowed, causing a delay in diagnosis, albeit not clinically significant in most patients. Although some PCE devices offer a live feed on the receiver or through an external device connected to the receiver, this also demands significant staff involvement for monitoring similar to HemoPill, if a patient cannot do the monitoring independently. In contrast, HemoPill provides real-time results plotted directly on the receiver without the need for an extra device. Moreover, HemoPill is less expensive than standard PCE in Germany. Recently, a study with another commercially available blood-detecting swallowable capsule has been published, showing promising results for detection of active bleeding in the upper gastrointestinal tract [5]. The availability of this second blood-detecting capsule heralds a new dawn of noninvasive bleeding detection in clinical practice.

Conclusions

In summary, HemoPill has the potential to serve as a noninvasive diagnostic adjunct tool for detection of gastrointestinal bleeding, especially in patients for whom extensive endoscopic diagnostics are not appropriate (e.g., comorbid or geriatric patients). Further studies (i.e., the “Rabbit”-Study, Study-ID: DRKS00026103) aim to clarify the potential of HemoPill as an

alternative to video capsule endoscopy in diagnosing bleeding in the middle gastrointestinal tract. We believe that in the future, the role of noninvasive diagnostics in detection of upper, middle, and lower gastrointestinal bleeding will increase.

Conflict of Interest

DQ has received travel and educational grant from Cook medical OC has acted as a consultant for Olympus PE, KS, WU, WES, CTR do not have any relevant potential conflict of interest

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