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Editorial

Changing the paradigm of capsule endoscopy: tempting... but no (not yet)

Referring to Rosa B et al. doi: 10.1055/a-2270-4601

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Abstract

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In this issue of *Endoscopy*, Rosa et al. present a study comparing efficacy and safety of pan-intestinal capsule endoscopy (PCE) using a double-headed capsule and same-day colonoscopy in patients with suspected midgut or lower gastrointestinal bleeding [11]. A total of 100 patients with iron-deficiency anemia or overt bleeding who underwent negative upper endoscopy were included. They were given extensive split-dose bowel cleansing with additional boosters prior to capsule ingestion in the morning; 10 hours later they underwent conventional colonoscopy. Findings of both examinations were compared. The results are in favor of PCE as a first-line procedure in cases of suspected mid or lower gastrointestinal bleeding, thanks to positive PCE findings in 46% of the patients, with excellent efficacy (96% sensitivity, 100% specificity, 96% negative predictive value, and 100% positive predictive value) and safety. Should this approach (PCE-first instead of colonoscopy) be adopted after negative upper endoscopy? Are we ready to dismiss conventional colonoscopy after negative PCE? Or should diagnostic PCE become the very first examination before submitting patients to more invasive conventional endoscopic procedures with exclusive therapeutic intent?

The idea is tempting: endoscopic visualization of the entire gastrointestinal tract in one single noninvasive examination, and redirection of invasive conventional endoscopy to a second-line therapeutic procedure. It was put forward 10 years ago, referring to the precedent of diagnostic magnetic resonance cholangiopancreatography, reducing endoscopic retrograde cholangiopancreatography to a purely therapeutic procedure [22]. In 2015, PCE became a reality for patients with Crohn's disease to evaluate mucosal healing in both the small bowel and the colon with a single examination [33]. Since then, more studies have illustrated the beneficial role of PCE in the diagnosis and follow-up of inflammatory bowel diseases [44]. PCE also proved useful in the investigation of obscure and overt gastrointestinal bleeding, with positive findings (both intestinal and colonic) reaching 60%–80% [55].

"...despite its potential strong points (e.g. being noninvasive, visualization of the entire gastrointestinal tract in one single examination), PCE in the setting of digestive bleeding also faces technical, practical, juridic, and financial drawbacks."

Based on these outcomes, PCE is suggested to take the lead in the algorithm of endoscopic explorations of the gastrointestinal tract in inflammatory bowel diseases and now also to exclude digestive blood loss. The reason for this PCE enthusiasm is found in its advantages: a noninvasive technique that allows endoscopic visualization of the entire gastrointestinal tract in one single examination and does not require technical expertise, in contrast to conventional endoscopy, and apart from intestinal stricture, there are no real safety issues involved. However, despite these potential strong points, PCE in the setting of digestive bleeding also faces technical, practical, juridic, and financial drawbacks.

If PCE takes the pole position for exploration of the gastrointestinal tract, every endoscopy unit needs the equipment and software platform to allow at least one PCE per day. Apart from this technical aspect, the endoscopy unit will need organizational revision. PCE requires training in the recognition and identification of pathological lesions throughout the gastrointestinal tract [66]. For the PCE-first paradigm, more people will need training, such as qualified nurses and technicians, as well as endoscopists, as suggested by ESGE [66]. When more attention and time is spent on PCE training, fewer indications and less training time remain for conventional endoscopy.

From a practical point of view, PCE is time consuming. The total time needed to perform PCE starts from the extensive bowel cleansing the day before, with additional boosters to ensure complete visualization of the small bowel and colon, which will be challenging in cases of active bleeding. Insufficient bowel preparation increases the risk of missing potentially hemorrhagic lesions and increases the rate of incomplete examinations, as illustrated in the Rosa et al. study [11]. The authors also show that ESGE quality criteria for PCE bowel cleansing are not met in patients with active bleeding, despite the rigorous cleansing protocol, representing an important drawback of the PCE-first use in patients with active bleeding [11] [77]. In the study, the duration of PCE recording was set at 10 hours, with only 76% of complete PCE (small bowel and colon) examinations [11]. Although most capsule devices allow real-time viewing, the time-consuming analysis of the total recording is done afterwards on the software platform (with or without the help of artificial intelligence). In total, this approach takes 3 days when ideal settings are met (bowel preparation on day 1, PCE on day 2, and video analysis on day 3), and this is only to diagnose the potential bleeding source, not to treat it. Any therapeutic conventional endoscopy will need to follow afterwards in a timely manner. Furthermore, this timeline does not consider urgent PCE application during the weekend. The timeline illustrates the practical hurdles of the PCE-first algorithm. ESGE guidelines suggest performing capsule endoscopy within 48 hours of the bleeding episode to increase the pick-up rate of positive findings, whereas in the Rosa et al. study, the majority of patients underwent PCE with subsequent colonoscopy within 2 weeks after the bleeding episode [11] [88]. The proposed algorithm looks tempting, but daily endoscopic practice cannot (yet) fulfill these standards.

The authors also discuss the beneficial financial aspect of a PCE-first approach, with the potential to reduce the number of colonoscopies by 43%, based on negative PCE findings in the colon [11]. Although the study was not designed to investigate the cost–benefit of the PCE-first approach, the topic certainly needs to be addressed in view of a possible paradigm change. However, capsule reimbursement criteria differ significantly across nations, rendering future cost–benefit studies relevant only to those countries involved in the study. Finally, there are currently no known malpractice claims described in the literature because of missed lesions by capsule endoscopy. The risk of missed lesions increases with the length of the recording, the reading speed, incomplete examinations, and with insufficient bowel cleansing. These factors all impact the PCE-first paradigm. Are we ready to dismiss colonoscopy after a negative PCE that does not fulfill all quality parameters? If not, the endoscopic community will continue to perform, whatever the sequential order, both upper and lower endoscopy and capsule endoscopy, in cases of suspected bleeding.

I congratulate Rosa et al. for their interesting study, as it opens the door to discussing clinical guidelines and algorithms; however, based on what is currently known, the door is still only ajar.

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