Role of colon capsule in colorectal cancer screening: lights and shadows

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The implementation of screening has greatly contributed to the decrease in incidence and mortality of colorectal cancer (CRC) in many developed countries over the past two decades. Screening from the age of 50 years prevents CRC by enabling the detection and removal of precancerous lesions (advanced adenomatous or serrated polyps) and reduces mortality through early detection (stages I and II) of curable CRC [1].

"...the safety of colon capsule endoscopy and its high sensitivity in detecting advanced colorectal neoplasia should be sufficient to place it within the group of second-tier screening imaging technologies, which could be offered in an opportunistic context and to individuals unwilling to undergo colonoscopy."

Currently, colonoscopy every 10 years and annual or biennial fecal immunochemical testing (FIT) are the two most extensively used screening strategies worldwide. Colonoscopy is considered the gold-standard screening method because it may detect and remove precancerous lesions in a single session; this procedure is the predominant test in the United States, where screening is mostly opportunistic. However, its use in programmatic screening is limited by its high demand for resources, which makes it unfeasible in countries with limited colonoscopy capacity. In addition, it is frequently perceived as a painful and dangerous technique, which explains its low adherence rates. On the other hand, FIT is an inexpensive and noninvasive two-step screening method (requiring a subsequent colonoscopy if the test is positive) that has acceptable accuracy in detecting early CRC and adenomas > 10 mm in diameter (advanced colorectal neoplasia [ACN]) when performed periodically, along with better adherence rates than colonoscopy [2]. It is the preferred test in countries advocating organized population-based screening. Other two-step screening procedures, such as sigmoidoscopy, computed tomographic colonography (CTC), and the multitarget stool FIT-DNA test (MT-sDNA), have been proposed as potential tools for primary screening. However, although randomized trials [3] and modeling studies [4] have shown that these tests reduce the mortality and incidence of CRC, these methods are rarely used in programmatic screening for a variety of reasons.

Second-generation colon capsule endoscopy (CCE) is a minimally invasive procedure with a diagnostic yield for ACN comparable to that of colonoscopy and superior to that of CTC. Although its main clinical indication is for patients with incom-

plete colonoscopy, CCE has features that suit it perfectly as a screening tool: it uses a painless orally ingested device that allows complete exploration of the colon without the need for sedation or air insufflation, and it can be performed on an outpatient basis. On the other hand, it has limitations that restrict its use for screening: first, it requires a more rigorous and uncomfortable bowel preparation process than colonoscopy; second, it has an elevated rate of incomplete procedures mostly due to a delayed transit time; third, its diagnostic yield for serrated polyps is poor compared with that of colonoscopy or MT-sDNA; fourth, the time it takes to download the recorded data to the workstation (~120 minutes) and the time needed to read the scan (~60 minutes) preclude same-day colonoscopy in the event of a positive finding; fifth, CCE requires experienced readers to guarantee a high rate of diagnostic accuracy; and sixth, its high cost (€600–800) gives it a competitive disadvantage against most of the available screening tests, mainly in the context of programmatic screening. However, few studies have analyzed the efficacy of CCE in the context of CRC screening.

In this issue of *Endoscopy*, Vuik et al. report the first systematic review on the feasibility of CCE as a screening tool in asymptomatic average-risk populations [5]. The analysis included 13 studies with a total sample of 2485 subjects. In five studies (1521 subjects), CCE was performed as a primary screening tool, whereas in the remaining eight studies (964 subjects), it was assessed as a filter for colonoscopy in individuals with a positive FIT. Most of the studies were observational studies comparing the performance of CCE with colonoscopy or CTC. Overall, the accuracy of CCE in detecting ACN was comparable to that of colonoscopy and superior to that of CTC when the exploration was complete. In addition, no major complications were reported. Based on these findings, the authors concluded that CCE should be considered as an alternative for colonoscopy in CRC screening programs, although the completion rate should be improved.

Apart from the high performance of CCE in detecting ACN, this systematic review also provides relevant information on the main barriers facing this technique: first, CCE failed to explore the entire colon in approximately one-third of participants due either to inadequate bowel preparation or to incomplete examinations, which forces subsequent colonoscopy in order to rule out missing neoplasia; second, the uptake of CCE as a primary screening test or as a filter in individuals with a positive FIT was 4.3 % and 5.0 %, respectively. Although more studies are needed to explore CCE screening adherence, these figures are far from the 65 % and 80 % adherence targets recommended by the European Guidelines [6] and the National CRC Round Table in the USA [7], respectively. In addition, it must be taken into account that the elevated cost of CCE makes it barely cost-effective. In fact, a French study showed that assuming a similar adherence rate to other screening tests, CCE is not cost-effective as a primary screening test [8].

Overall, these data suggest that CCE is still not ready to be considered a valid tool in organized population-based screening. In fact, the European Society of Gastrointestinal Endoscopy and the European Society of Gastrointestinal and Abdominal Radiology do not recommend CCE as a first-line CRC screening test in their recent guidelines [9]. In order to reconsider this recommendation, more evidence from large multicenter prospective trials is required, and the main barriers mentioned above should be minimized. The incorporation of new technologies (magnetically controlled or self-propelled devices) and artificial intelligence may soon improve capsule maneuverability and the diagnostic yield for serrated polyps and small malignant polyps, reducing reading times and dependence on experienced readers. New bowel cleansing regimens should also be implemented to make the procedure better accepted and effective. In addition, significant further cost reductions are needed for CCE to be a cost-effective option in population-based CRC screening.

Nonetheless, the strengths reported in this systematic review regarding the safety of CCE and its high sensitivity in detecting ACN should be sufficient to place CCE within the group of second-tier screening imaging technologies, which could be offered in an opportunistic context and to individuals unwilling to undergo colonoscopy.

Competing interests

The authors declare that they have no conflict of interest.

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