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Looking forwards: not necessarily the best in capsule endoscopy?

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Title: First clinical trial of a newly developed capsule endoscope with panoramic side view for small bowel. A pilot study

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Summary

Since its first description in the early 2000s [1], the capsule endoscope (CE) has been consolidated in all diagnostic algorithms for the assessment of the small-bowel [2]. Nevertheless, the issue of the diagnostic yield (DY) in wireless, hence non-steerable, CE continues to trouble physicians [3-6]. It is already known that a broader angle (field) of view is associated with higher DY [7-10]. Most of the current CE models/systems employ a single-dome viewing philosophy, in which the lens with image sensor and light source are aligned in a single (and in theory the moving) direction, with a field of vision that varies 140°-170° [2]. Therefore, the lens should be of a wide-angle type, often associated with image distortion. Moreover, a combination of other factors such as the speed of small-bowel transit [8,11], and the cleansing of the small bowel [12] appear to significantly impact on the DY.

Therefore, we read with great interest the study on the use of a newly developed CE (CapsoCam®SV-1; Capso Vision™, Saratoga, CA, USA) with panoramic (side-viewing) capability by Friedrich *et al* [13]. CapsoCam® boasts an innovative design that employs four cameras (CMOS), each with an approximately 90° field of view, facing the sides of the capsule. Each camera obtains 5 frames-per sec (fps) for the first 2 h and thereafter 3 fps, resulting in 20 and 12 fps, respectively. CapsoCam®SV-1 (11x31mm) dimensions are similar to the PillCam®COLON (Given® Imaging Ltd, Yoqneam, Israel). Theoretically, the obtained images are more stable due to reduced camera motion and also reduced mucosal movement [14]. Moreover, the true wire-free (a step beyond "wireless") design aims to enhance patient comfort and minimize procedural / maintenance costs [13,14]. Interestingly, CapsoCam®SV-1 employs motion sense technology, powered by an auto illumination controller to provide optimal light as required by the cameras, and has a battery life of ~15 h [13,14]. Furthermore, the Flash EPROM storage device does not generate or transmit radiofrequency (RF) waves, although recent evidence confirms the safety of capsule endoscopy in patients with implanted devices [15,16].

In their study, Friedrich *et al* [13] recruited 33 patients with a mean age of 45 years, referred for CE for a combination of indications including: anemia: 17, inflammatory bowel disease: 12, abdominal pain: 6, MALToma: 1 and elevated tumor markers: 2.

One group of patients (n=23), swallowed the capsules immediately following colonoscopy. They were prepared with 150 mL of Sodium Picosulfate (SP) and 3-4 L of water. They were allowed clear fluids. The morning of the procedures they were given 150 mL SP and 1 L of water. The other group (n=8), who went straight on to CE were prepped with 2 L of polyethylene glycol solution in the afternoon before the examination. All patients received 20 mg of Metoclopramide and 160 mg of Simethicone 30 min before ingestion of the capsule. Average cleanliness of the small bowel was 3.3 ±0.5 (on a 1-4 scale). The quality of the images was scored by 3 independent gastroenterologists and the mean overall score was 3.6 ±0.06 (on a 0-4 scale) with 91.4% of images evaluated as good or excellent.

The authors used the duodenal papilla (ampulla of Vater, AoV) as the only landmark in small-bowel. Identification of the duodenal papilla was possible in 22 patients (71%). The AoV was to be seen in 3.1±1.8 frames (median: 2.0 frames). Small-bowel transit time was 258 ±136 min (range: 40- 621

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min). Mean number of small-bowel frames was 14.209±7.671. Video review time was 48.8 ±11.4 min.

Opinion

One of the majors advances in controlling the capsule movement, hence improving the user/device interface during the examination, is external capsule control with some form of steering handle, but the experiments are still underway [17,18]. In the meantime, we are forced into using landmarks such as the Z-line and /or the AoV (major papilla) [2,19,20] as surrogate markers of segmental DY in CE. Interestingly, the AoV lies anatomically on the medial aspect of the duodenal sweep [20,21]. Therefore, the inability to visualize it seems an inherent limitation of CE [22]. This is because the rigid capsule shell of any single head-viewing capsule tends to point to the outer aspect of luminal curves, especially in areas like the proximal small-bowel where the capsule movement is much faster and uncontrolled [9,20,21]. Therefore, external control of the capsule is expected to mark the next significant forward-leap in wireless endoscopy.

Until then though, innovative ideas such as the placement of imagers in the middle of a capsule (spaced 90° apart), should be regarded as a welcome new approach in wireless endoscopy. These cameras offer a panoramic view of the intestinal mucosa (with ~10° overlap) and capture high resolution images. As the motion of the mucosa is constrained to a minimum, it is plausible to consider that software for three-dimensional representation/reconstruction (like the fly-through mode of CT colon) could be applicable with this system [23,24]. Moreover, if and when real time data transfer is realized, a fantastic opportunity for integration of automatic lesion recognition software will be available [25,26].

In a recent study [20], we examined the detection rate of the AoV in 619 CE videos (262 PillCam®SB1, 148 PillCam®SB2 and 209 MiroCam®). The AoV was identified only in 9.5% (59 CE examinations), with no statistical difference between the CE systems (P= 0.665). Furthermore, bile spout was the single factor associated with a higher AoV detection (P= 0.003). Earlier, we had shown that the presence of 2 heads (esophageal capsules) make a slower reading rate and are also associated with higher detection rate of the AoV [10], results quite consistent with those obtained from other groups [2]. Conversely, Friedrich *et al* [13] showed an impressive 71% AoV detection rate in this CapsoCam® study. Extrapolating the DY of this new capsule in proximal segments of the small bowel appears extremely promising.

Perhaps one of the downsides of the CapsoCam® platform (both in regards to patient comfort and examination governance) is the fact that patients are required to retrieve the capsule in order to have a "successful" test. In fact, a purpose-designed retrieval kit, where the capsule is picked up from the collection pan with the use of a magnetic wand, is part of the capsule kit. The capsule is then placed in the CapsoRetrieve Vial and returned to the reading center. Furthermore, the CapsoView™ Software may be a surprise for reviewers used to 'traditional' CE review software. Especially those with prior brain-acclimatization to conventional endoscopy images, might find it unwieldy looking as an "open-up" bowel surface of the images from the four cameras are displayed in one row, a kind of bird's eye view.

In conclusion, innovative capsule designs such as CapsoCam® and Sayaka® have been developed and/or presented. The latter, product of RF SYSTEM (RF Co., Ltd., Nagano, Japan), was initially announced in December 2005 but has since been under development. It supersedes the basic technology embedded NORIKA 3[27], the first "battery-free endoscopic capsule" announced to the market in December 2001. It features 2 actuators on each side that have the ability to rotate the centrally placed lens. Power is supplied wirelessly from an external source. Approximately 870,000 images (up to 20 photos are taken per lens 360° rotation), are sent to a receiver located near the body. Image mosaic technology is then used to stitch the images together into a flat, high-resolution rectangular map of the small-bowel mucosa, which sounds quite similar to the current review of the interface of CapsoView™ Software. Essentially, manoeuvrability and improved optics sound like two sides of the same coin i.e. improvement in DY. Furthermore, in agreement to Friedrich et al, these authors believe that in endoscopy the innovation of the past is the challenge of the present and the mere convention of the (near) future.

References

1. Iddan G, Meron G, Glukhovsky A, et al. Wireless capsule endoscopy. *Nature* 2000;**405**:417.
2. Koulaouzidis A, Rondonotti E, Karargyris A. Small-bowel capsule endoscopy: A ten-point contemporary review. *World J Gastroenterol* 2013;**19**:3726-3746.
3. Mavrogenis G, Coumaros D, Renard C, et al. Jejunal gastrointestinal stromal tumor missed by three capsule endoscopies. *Endoscopy* 2011;**43**:735-736.
4. Postgate A, Despott E, Burling D, et al. Significant small-bowel lesions detected by alternative diagnostic modalities after negative capsule endoscopy. *Gastrointest Endosc* 2008;**68**:1209-1214.
5. Ross A, Mehdizadeh S, Tokar J, et al. Double balloon enteroscopy detects small bowel mass lesions missed by capsule endoscopy. *Dig Dis Sci* 2008;**53**:2140-2143.
6. Zheng Y, Hawkins L, Wolff J, et al. Detection of lesions during capsule endoscopy: physician performance is disappointing. *Am J Gastroenterol* 2012;**107**:554-60.
7. Triantafyllou K, Papanikolaou IS, Papaxoinis K, et al. Two cameras detect more lesions in the small-bowel than one. *World J Gastroenterol* 2011;**17**:1462-1467.
8. Triantafyllou K. Can we improve the diagnostic yield of small bowel video-capsule endoscopy? *World J Gastrointest Endosc* 2010; **2**:143-146.
9. Koulaouzidis A, Douglas S, Plevris JN. Heads or tail orientation in small-bowel capsule endoscopy: 2 capsule models with 2 reviewers. *Dig Dis Sci* 2012;**57**:1102-1103.
10. Koulaouzidis A, Douglas S, Plevris JN. Identification of the ampulla of Vater during oesophageal capsule endoscopy: two heads and viewing speed make a difference. *Eur J Gastroenterol*

Hepatol 2011;**23**:361.
11. Westerhof J, Koornstra JJ, Hoedemaker RA, et al. Diagnostic yield of small bowel capsule endoscopy depends on the small bowel transit time. *World J Gastroenterol* 2012;**18**:1502-1507.
12. Rokkas T, Papaxoinis K, Triantafyllou K, et al. Does purgative preparation influence the diagnostic yield of small bowel video capsule endoscopy?: A meta-analysis. *Am J Gastroenterol* 2009;**104**:219-227.
13. Friedrich K, Gehrke S, Sieg A. First clinical trial of a newly developed capsule endoscope with panoramic side view for small bowel. A pilot study. *J Gastroenterol Hepatol* 2013 May 22. DOI: 10.1111/jgh.12280. [Epub ahead of print]
14. http://50.87.144.56/~v3biz/index.php [last assessed 2nd September 2013]
15. Harris LA, Hansel SL, Rajan E, et al. Capsule endoscopy in patients with implantable electromedical devices is safe. *Gastroenterol Res Pract* 2013;**2013**:959234.
16. Bandorski D, Keuchel M, Brück M, et al. Capsule endoscopy in patients with cardiac pacemakers, implantable cardioverter defibrillators, and left heart devices: a review of the current literature. *Diagn Ther Endosc* 2011;**2011**:376053.
17. Hale MF, Drew K, Baldacchino T, et al. Gastroscopy without a gastroscope! Feasibility in a porcine model using a magnetic capsule. *Gut* 2013;**62**(Suppl 1):A156.
18. Keller J, Fibbe C, Volke F, et al. Inspection of the human stomach using remote-controlled capsule endoscopy: a feasibility study in healthy volunteers (with videos). *Gastrointest Endosc* 2011;**73**:22-28.
19. Koulaouzidis A. Upper oesophageal images and Z-line detection with 2 different small-bowel capsule systems. *World J Gastroenterol* 2012;**18**:6003-6004.
20. Koulaouzidis A, Plevris JN. Detection of the ampulla of Vater in small bowel capsule endoscopy: experience with two different systems. *J Dig Dis* 2012;**13**:621-627.
21. Cass OW. Is half-knowledge worse than ignorance? *Gastrointest Endosc* 2006;**64**:542-543.
22. Selby WS, Prakoso E. The inability to visualize the ampulla of Vater is an inherent limitation of capsule endoscopy. *Eur J Gastroenterol Hepatol* 2011;**23**:101-103.
23. Koulaouzidis A, Karargyris A, Rondonotti et al. Three-dimensional representation software as image enhancement tool in small-bowel capsule endoscopy: a feasibility study. *Dig Liver Dis* 2013 Jul 10. doi:pii: S1590-8658(13)00213-2. 10.1016/j.dld.2013.05.013. [Epub ahead of print]
24. Kolar A, Romain O, Ayoub J, Viateur S, Granado B. Prototype of video endoscopic capsule with 3-D imaging capabilities. *IEEE Trans Biomed Circuits Syst* 2010;**4:**239-249.
25. Iakovidis DK, Maroulis DE, Karkanis SA. An intelligent system for automatic detection of gastrointestinal adenomas in video endoscopy. *Comput Biol Med* 2006;**36**:1084-1103.
26. Iakovidis DK, Tsevas S, Polydorou A. Reduction of capsule endoscopy reading times by unsupervised image mining. *Comput Med Imaging Graph* 2010;**34**:471-478.
27. http://www.rfsystemlab.com/en/sayaka/ [last assessed 2nd September 2013]