**Name of journal: World Journal of Gastroenterology**

**ESPS Manuscript NO: 10492**

**Columns: OBSERVATIONAL STUDY**

**Capsule endoscopy capture rate: Has 4 frames-per-second any impact over 2 frames-per-second?**

Fernandez-Urien I *et al.* Capsule endoscopy: More frames-per-second, higher accuracy?

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**Received:** April 2, 2014 **Revised:** May 20, 2014

**Accepted:** June 26, 2014

**Published online:**

**Abstract**

**AIM**: To compare the current capsule and a new prototype at 2 and 4 frames-per-second, respectively, in terms of clinical and therapeutic impact.

**METHODS**: One hundred patients with an indication for capsule endoscopy were included in the study. All procedures were performed with the new device (SB24). After an exhaustive evaluation of the SB24 videos, they were converted to “SB2-like”videos for their evaluation. Findings, frames per finding and clinical and therapeutic impact derived from videos visualization were analyzed. Kappa index for interobserver agreement and*χ*2 and Student´s t tests for qualitative/quantitative variables, respectively, were used. Values of *P* under 0.05 were considered statistically significant.

**RESULTS**: Eighty-nine out of 100 cases included in the study were finally included in the analysis. The SB24videos detected the anatomical landmarks (z-line and duodenal papilla) and lesions in more patients than the “SB2-like”videos. On the other hand, the SB24videos detected more frames per landmark/lesion than the “SB2-like”videos. However, these differences were not statistically significant (*P* > 0.05). Both clinical and therapeutic impacts were similar between SB24 and “SB2-like”videos (*K* = 0.954). The time spent by readers was significantly higher for SB24videos visualization (*P* < 0.05) than for “SB2-like” videos when all images captured by the capsule were considered. However, these differences become notsignificant if we only take into account only small bowel images (*P* > 0.05).

**CONCLUSION**: More frames-per-second detects more landmarks, lesions and frames per landmark/lesion but is time consuming and has a very low impact on clinical and therapeutic management.

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**Key words:** Capsule endoscopy; Small bowel; Diagnostic accuracy; Frames; Lesions; Landmarks.

**Core tip:** The capsule endoscopy has demonstrated to be very accurate for small bowel lesions detection. Currently, most of the capsule endoscopes take 2 frames-per-second. Whether more frames-per-second could increase its diagnostic accuracy hasn´t been previously investigated. The present study demonstrates that more frames per secondis time consuming and has a very low impact in clinical and therapeutic management.

Fernandez-Urien I., Carretero C., Borobio E., Borda A., Estevez E., Galter S., Gonzalez-Suarez B., Gonzalez B., Lujan MS., Martinez JL., Martínez V., Menchen P., Navajas J., Pons V., Prieto C., Valle J. Capsule endoscopy capture rate: Has 4 frames-per-second any impact over 2 frames-per-second? *World J Gastroenterol* 2014; In press

**INTRODUCTION**

After 12 years of “life”, the capsule endoscopy has demonstrated to be an accurate, painless and safe procedure for patients with suspected small bowel diseases[1-3]. It has also been proven to be superior to other diagnostic modalities such as small bowel follow-through, CT-enterography and push enteroscopy in obscure gastrointestinal bleeding, inflammatory bowel disease and other clinical scenarios being currently considered the new state-of-the-art procedure for small bowel visualization[4-8]. In fact, more than 2000000 capsule procedures have been performed worldwide (unpublished data). Due to its excellent acceptance by both patients and physicians, Given Imaging (Yoqneam, Israel) decided to introduce some modifications on the first generation of small bowel capsules (M2A) in order to improve its diagnostic accuracy. Then, firstly the PillCam™ SB in 2004 and secondly, the PillCam™ SB2 in 2007, were developed. However, the capsule endoscopy is still not perfect and has some limitations. On one hand, some lesions are missed probably due to the speed and/or orientation of the capsule in some segments of the gastrointestinal tract. On the other hand, some lesions are detected by the capsule in just one frame leading to difficulties in their characterization that may have a negative impact on final diagnosis. Despite there are not available data to support it, one solution to these limitations could be increasing the frame rate detection of the capsule. Based on this hypothesis, the aims of this study were to evaluate the differences between a new prototype of capsule endoscopy that takes 4 images per second versus the current capsule endoscopy that takes 2 frames per second in terms of findings, diagnostic and therapeutic impact.

**MATERIALS AND METHODS**

The present study was conducted at 10 Spanish institutions. Institutions and patients included per institution are shown in Table 1.

***Patients***

One hundred (*n* = 100) consecutive patients who had indication and no contraindications for capsule endoscopy were prospectively included in the study. Before capsule ingestion all patients received a fully oral explanation of both study and capsule endoscopy procedure and were asked to sign an informed consent form. This study was designed under the principles of the Declaration of Helsinki and was approved by the institutional review boards.

***Methods***

After written acceptation to be included in the study, all patients swallowed the PillCam™ SB24 (Given Imaging Ltd, Yoqneam, Israel). The main difference between PillCam™ SB24 and PillCam™ SB2 is the rate of images per second taken by the capsule, 4 instead of 2. Other technical specifications of the PillCam™ SB24 are shown in Table 2. Capsule appearance, sensor arrays, data recorders and software used in all procedures were exactly the same than those used in routine practice. The day before capsule ingestion all patients were asked to have (1) a low fiber diet; (2) 2 liters of polyethylene glycol; and (3) a minimum of 8 hours fast prior capsule ingestion. Then, all patients swallowed the capsule in the right supine position in order to obtain good images of the esophagus and Z-line. After capsule ingestion all patients were discharged from the hospital and asked to come back 10 h later. Laxatives and/or prokinetics were permitted but the use of this products had to be notified to the study coordinator. After downloading process had finished, 3 independent capsule endoscopy-experienced endoscopists reviewed the videos at 4 frames per second in order to detect all the lesions present in the videos. All readers were asked to review all the images of each one of the videos including those obtained in the esophagus, stomach and colon. An expert panel reviewed all findings and only clinically significant lesions were selected for the purpose of the study. Those doubtful or minor lesions were not considered in the analysis. Then, all videos were labeled, recorded in portable hard discs and sent to a technician in Israel who converted the videos from 4 frames per second to 2 frames per second simulating conventional SB2 videos (“SB2-like videos”). Three independent readers who did not know the results derived from the first visualization, again reviewed all converted videos. Again, only clinically significant findings were considered and those doubtful findings were discussed by an expert panel. For each one of the videos reviewed, these were the variables noted: patient baseline characteristics, procedure indication, Z-line, duodenal papilla and lesion visualization, number of frames per image/lesion selected, final diagnosis, need for more diagnostic procedures, final treatment and reading times. The present study is a prospective, multicenter and comparative study where quantitative data are shown as mean and range or standard deviation and qualitative data as simple proportions. The interobserver agreement analysis was performed using the kappa index and the benchmarks considered by Fleiss[9] (< 0.40 poor agreement; 0.40-0.75 good agreement; > 0.75 excellent agreement). On the other hand, the comparative analysis was performed using the *χ*2 test for qualitative variables and the Student´s t test for quantitative variables. Values of *P* under 0.05 were considered statistically significant.

**RESULTS**

A total of 100 procedures were performed but only 89 (89%) were included in the analysis. Eleven procedures (11%) were withdrawn due to technical issues and protocol violations: one capsule was retained in the stomach, 6 SB24 videos were not converted to “SB2-like” videos because the raw data were not correctly downloaded and 4 patients did not ingested the PEG solution.

***Patient and procedure baseline characteristics***

The mean age of patients included in the study was 51.6 years (range 21-84), 35 (39.3%) were males and 54 (60.7%) females. Procedure indications were as follows: obscure gastrointestinal bleeding in 55 (61.8%), inflammatory bowel disease in 19 (21.3%), malabsortion in 5 (5.6%), tumors in 5 (5.6%) and abdominal pain in 5 (5.6%) patients. The capsule was ingested by the patients in the right supine position in 74 (83%) of the cases and the cecum was achieved in 80 patients (90%).

***Findings-Overall view***

**Anatomy:** The Z-line and duodenal papilla were detected in 53/89 (59.5%) and 7/89 (7.8%) patients and in 616 (11.6 frames per positive procedure on average) and 35 frames (5 frames per positive procedure on average), respectively.

***Pathology***

A total of 257 different lesions and 3291 pathologic frames were detected. The distribution of lesions and pathologic frames depending on their localization are shown in Table 3.

***Comparative analysis***

Comparative analysis has been summarized in Tables 4-9 and illustrated in Figures 1 and 2.

**Anatomy:** The SB24 detected both Z-line and duodenal papilla in more patients than the “SB2-like”: 53 (59.5%) *vs* 45 (50.6%) and 7 (7.9%) *vs* 6 (6.7%) out of 89 patients included in the analysis, respectively. However, these differences were not statistically significant (*P* > 0.05). Moreover, there was an excellent agreement between SB24 and “SB2-like” in selecting those patients with at least one image of the z-line and duodenal papilla (kappa index 0.820 and 0.917, respectively). There were no cases with positive findings on “SB2-like” videos and negative on SB24. Furthermore, the SB24 captured more frames of both z-line (overall 616 and average 11.6 ± 20.4 for SB24versus overall 391 and average 8.6 ± 10.6 for “SB2-like”; *P* > 0.05) and duodenal papilla (overall 35 and average 5.0 ± 2.0 for SB24 *vs* overall 15 and average 2.5 ± 1.4 for “SB2-like”; *P* < 0.05). Focused on the quality of the images detected of z-line (percent of Z-line detected), there were not significant differences between both capsules (*P* > 0.05).

***Pathology***

**Per-patient analysis:** Almost all patients with lesions, despite their location, were detected by both methods resulting in no significant differences between them (*P* > 0.05). Moreover there was an excellent agreement between the videos for detecting patients with lesions (kappa index from 0.9 to 1.0; excellent agreement). There were not positive cases in “SB2-like” videos that were negative in SB24 videos.

**Per-lesion analysis:**Most of the lesions detected in the videos at 4 frames per second were also detected in the “SB2-like” videos resulting in no statistically significant differences. Moreover, there were no cases with positive findings on “SB2-like” videos and negative on SB24. In fact, the SB24 detected 257 lesions (2.9 ± 3.8 on average per patient) and the “SB2-like” 244 (2.7 ± 3.5 on average per patient). Only when considering the esophagus and small bowel, the SB24 videos detected more lesions compared to “SB2-like” (17 *vs* 14 in the esophagus and 193 *vs* 183 in the small bowel). Furthermore, the SB24 captured more frames of eachlesion despite its localization but these differences were not statistically significant (*P* > 0.05). All lesions (100%) lost in the “SB2-like” videos were lesions detected in 1-2 frames in the SB24 videos. There were not lesions detected in more than 2 frames in SB24 videos that were lost in “SB2-like” videos.

***Time spent***

The time spent for video reading was higher for the SB24 videos. However, this differences were significant only in those cases where all the images (from mouth to the last procedure image) where reviewed (average time of 39.6 ± 15.8 for SB24 *vs* 29.5 ± 12.4 for SB2-like;*P* < 0.05).

***Clinical and therapeutic impact***

When clinical and therapeutic impact was analyzed, it was seen that the agreement between SB24 and “SB2-like” videos was excellent (*K* = 0.954). Only in 1 case (1.12%) the use of SB24 instead of SB2 capsule lead to a different diagnose and management, as there was a single frame showing Barret´s esophagus that was missed in the “SB2-like video.

**DISCUSSION**

The capsule endoscopy has opened a new era in small bowel examination. In fact, its diagnostic accuracy is very high particularly in those patients with obscure gastrointestinal bleeding and inflammatory bowel disease, being currently the first line diagnostic tool for small bowel suspected diseases[1-8]. Despite its excellent performance, capsule endoscopy has some limitations. On one hand, it has been demonstrated that some lesions can be missed by the capsule endoscopy[10-12]. Although these false negatives could be related to non-accurate readings, the presence of blind areas and fast transit times in some segments could be the main reasons in most of the cases. On the other hand, it is also known that false positive lesions could be detected during small bowel capsule endoscopy leading to unnecessary diagnostic and therapeutic procedures. Most of the false positives are due to doubtful images detected in a low number of frames or even in just one frame. During most of the capsule endoscopy training programs, one general rule that is usually given to trainees is to avoid those diagnoses based only in one frame. In these situations they are usually asked to use the mouse scroll in order to find more frames of the suspected image and make a correct diagnosis. However, sometimes it is not possible because there is only one frame of the suspected lesion and the diagnose has to be based on it. So, it makes sense that the number of frames of suspicious lesions is directly related to correct characterizations and then, to correct diagnoses. Currently, there are 5 capsule endoscopes in the market: PillCam SB2 (Given Imaging Ltd., Yoqneam, Israel), EndoCapsule (Olympus Medical Systems Corp., Tokyo, Japan) and OMOM (Jianshan Science and Technology Group Co., Ltd., Chongqing, China)small bowel capsule systems which capture 2 frames per second, Mirocam small bowel capsule system (Intromedic Ltd, Seoul, Korea) that can capture 3 frames per second and the recently developed CapsoCam capsule (CapsoVision Inc., Sillicon Valley, CA, United States) that captures 3-5 frames per second. Moreover, since 2007 there are capsules designed for the study of the colon that have 2 optical heads taking 4 frames per second (PillCam™ COLON1; Given Imaging Ltd, Yoqneam, Israel) and recently from 4 to 35 frames per second (PillCam™ COLON2; Given Imaging Ltd, Yoqneam, Israel). It is well known that some physicians use the PillCam™ COLON/2 for the study of the small bowel considering the higher number of frames per second captured. However, it is not still clear if it increases the diagnostic accuracy[13,14]. Previous reports comparing the Mirocam and the PillCam SB capsules shown no benefits from 3 over 2 frames per second capture rate, in terms of diagnostic accuracy[15,16]. To our knowledge, the present study is the first study that compares the clinical and diagnostic impact of more frames per second capture rate using the same capsule endoscope. The present study compares a new prototype of small bowel capsule endoscopy by Given Imaging that takes 4 frames per second. One of the positive aspects of this study is that we could compare the number of frames of the same lesions captured in both videos. We did not perform 2 examinations to each one the patients. We performed all procedures with the new prototype of the capsule (4 frames per second) and then, the videos were sent to Given Imaging in order to be converted in conventional videos at 2 frames per second (“SB2-like”). Then, we were able to compare anatomic landmark visualization, lesions detection and frames per lesion in the same images and in both, 4 frames and 2 frames per second videos. On the other hand, the present study focused mainly on lesions but also on anatomic landmarks because in daily practice it is quite frequent to find lesions there such as GERD lesions, Barrett esophagus, hiatal hernia and tumors[17-19]. In order to obtain the best images of the esophagus, all patients swallowed the capsule in the right supine position as it is demonstrated to be the best approach for this purpose[20,21]. Moreover, this study analyzed not only lesions located at the small bowel, but also in esophagus, stomach and colon. For that purpose, all patients underwent PEG administration prior to capsule ingestion and all readers were requested to read all the images contained in the video, that means, from mouth to last video image. We did not find significant differences in the detection of anatomy and lesions between both capsules. SB24 and “SB2-like” detected anatomical landmarks in a very similar number of patients. However, there were differences in both, number of frames per landmark and quality of images detected. In fact, the 4 frames per second capsule detected more frames of the z-line and duodenal papilla but these differences were not significant. On the other hand, the same situation was observed when lesions were analyzed. Again, the SB24 detected more patients with lesions and more frames per lesion, especially in those located at the small bowel. However, these differences were not statistically significant. All lesions lost in “SB2-like” videos were lesions detected in 1-2 frames and that means that the benefits of 4 frames per second over 2 frames per second could be expected when small, isolated and esophageal/duodenal (fast transits) lesions are present. Obviously, our analysis resulted in no great differences in clinical and therapeutic impact except for one patient where the SB24 detected a Barrett´s esophagus that was missed by the “SB2-like”. In fact, this lesion was only visualized in just one frame. Once the statistical analysis was completed it seemed that although no significant differences between both capsules were found, the tendency (especially for small bowel lesions) was to reach statistically significant differences. This could be the main limitation of the study. This was a pilot study were, initially, 100 patients were included but this sample size was not enough to reach statistical differences. The future should bring new studies in larger populations in order to obtain solid conclusions of the benefit of using more frames per second in small bowel examinations. The use of more frames per second means more images to review and longer reading times. The present study demonstrates that the reading times were significantly longer when the videos were reviewed from mouth to the last video image. There were not significant differences when only small bowel was read. The reading times are an important issue of the capsule endoscopy. On one hand, physicians are usually working under pressure in public hospitals and there is no chance for time-consuming procedures. On the other hand, although it is not published, the time spent in video reading is inversely proportional to reader accuracy. It may be helpful to modify the software in order to delete similar images and consequently, decrease reading and also video downloading times.

In summary, this study demonstrates that there is no clinical and therapeutic impact derived from the use of a 4-frames per second capsule over the conventional one. However, it is also shown that more frames per second, which takes more time to the readers, gives more images of the same lesion/image, specially in the small bowel and this could be helpful in some situations. Future studies in larger series should be done in order to confirm our results.

**COMMENTS**

***Background***

Most of the capsule endoscopes take 2 frames per second during 8-10 hours approximately. However, they still miss lesions.

***Research frontiers***

Whether more frames-per-second could increase the diagnostic accuracy of capsule endoscopy hasn´t been previously investigated.

***Innovations and breakthroughs***

The clinical and therapeutic impact of 4 frames-per-second over 2 frames-per-second is very low. Moreover, the video reading takes more time.

***Applications***

Although more frames-per-second should not be recommended routinely, it could be helpful in fast transit segments such as esophagus or duodenum.

***Terminology***

Frames-per-second is the term used to describe the number of images taken by capsule endoscopy. Most of small bowel capsule endoscopes take 2 images-per-second (*i.e.,* 2 frames-per-second) during 8-10 h.

***Peer review***

This article presents interesting data concerning an old issue about the need for more frames-per-second during small bowel capsule endoscopy.

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**P-Reviewers:**AurelloP,Dietrich CF**S-Editor:**Qi Y

**L-Editor: E-Editor:**

**Table 1 Institutions and patients included per institution**

|  |  |
| --- | --- |
| **Institution** | ***n*** |
| Hospital de Navarra | 8 |
| Clinica Universidad de Navarra | 5 |
| Hospital Gregorio Marañon | 10 |
| Hospital Juan Canalejo | 10 |
| Hospital Puerta de Hierro | 9 |
| Hospital del Mar | 8 |
| Complejo Hospitalario de Toledo | 9 |
| Hospital La Fe | 10 |
| Hospital General de Valencia | 10 |
| Mutua de Tarrassa | 10 |
| Total | 89 |

**Table 2 PillCam SB24 specifications**

|  |  |
| --- | --- |
| Physical dimensions | 26 mm ×11 mm |
| Weight | 2.89 ± 0.15 g |
| Number of imaging heads | 1 |
| Imager type | CMOS |
| Image capture rate | 4 frames per second |
| Optical illumination | 4 white light emitting diodes with ALC |
| Field of view | 156° – working distance of 4.5 mm |
| Depth of field | 0-30 mm |
| Mucosa área images at 4.5 mm | Approximately 1100 mm2 |
| Magnification | 1.8 |
| Min. detectable object size | 0.1 mm |
| Min. operation time | 7 h and 58 min |
| Max. operation time | 9:00 h |
| Shelf life | 10 months after manufacturing date |
| Transmitter frequency | 434.1 MHz |
| Battery type | Silver oxide, non-toxic |
| Storage temperature | 0-30° |
| Activation | Magnetic, automatic from blister |

**Table 3 Overall numbers of lesions and abnormal frames detected *n* (%)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Lesions | | Frames | |
| Total |  | Total |  |
| Esophagus | 17 | (6.6) | 132 | (4) |
| Stomach | 30 | (11.6) | 617 | (19.1) |
| Small bowel | 193 | (75) | 2227 | (69) |
| Colon | 17 | (6.6) | 249 | (7.7) |
| Total | 257 | (100) | 3225 | (100) |

**Table 4 Comparative analysis of ladmarks detection *n* (%)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **SB24** | | **“SB2-like”** | | ***P*value** | ***K*value** |
| **patients** |  | **patients** |  |
| Z-line | 53 | (59.5) | 45 | (50.6) | NS | 0.820 |
| Papilla | 7 | (7.9) | 6 | (6.7) | NS | 0.917 |

NS: Not significant.

**Table 5 Comparative analysis of frames per landmark**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **SB24** | | **“SB2-like”** | | ***P*value** |
| **Frames** | **Mean ± SD** | **Frames** | **Mean ± SD** |
| Z-line | 616 | 11.6 ± 20.4 | 391 | 8.6 ± 10.6 | NS |
| Papilla | 35 | 5.0 ± 2.0 | 15 | 2.5 ± 1.4 | <0.05 |

NS: not significant; SD: standard deviation

**Table 6 Comparative analysis of quality of images detected**

|  |  |  |  |
| --- | --- | --- | --- |
| **Quality1** | **SB24** | **“SB2-like”** | ***P*value** |
| **Mean ± SD** | **Mean ± SD** |
| 91.94 ± 21.82 | 88.01 ± 34.87 | NS |

NS: Not significant; SD: Standard deviation. 1Defined as percent of z-line detected by the capsule.

**Table 7 Lesions detection: Per-patient analysis *n*(%)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **SB24** | | **“SB2-like”** | | ***P* value** | ***K*** |
| **patients1** |  | **patients1** |  |
| Esophagus | 15 | (23.0) | 14 | (22.2) | NS | 0.9 |
| Stomach | 18 | (27.7) | 18 | (28.5) | NS | 1 |
| Small bowel | 59 | (90.7) | 59 | (93.6) | NS | 1 |
| Colon | 11 | (16.9) | 11 | (17.4) | NS | 0.9 |
| Total | 65 | (100) | 64 | (100) | NS | 0.9 |

1Patients could be included in more than one cathegory. NS: Not significant.

**Table 8 Lesions detection: Per-lesion analysis**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **SB24** | | **“SB2-like”** | | ***P* value** |
| **Lesions** | **Mean ± SD** | **Lesions** | **Mean ± SD** |
| Esophagus | 17 | 0.2 ± 0.4 | 14 | 0.1 ± 0.4 | NS |
| Stomach | 30 | 0.3 ± 0.8 | 30 | 0.3 ± 0.8 | NS |
| Small Bowel | 193 | 2.2 ± 3.1 | 183 | 2.1 ± 2.8 | NS |
| Colon | 17 | 0.2 ± 0.6 | 17 | 0.2 ± 0.6 | NS |
| Total | 257 | 2.9 ± 3.8 | 244 | 2.7 ± 3.5 | NS |

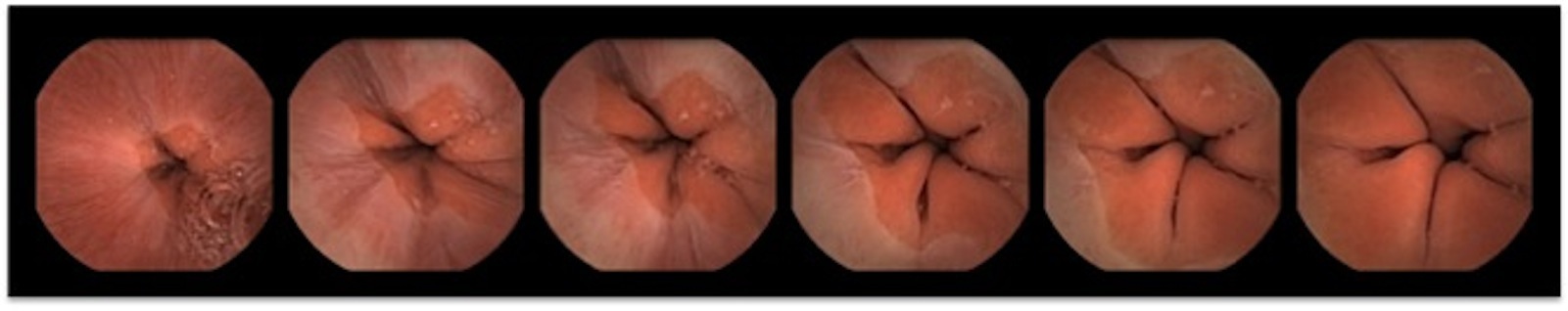
NS: Not significant; SD: standard deviation.

**Table 9 Comparative analysis of frames per lesion**

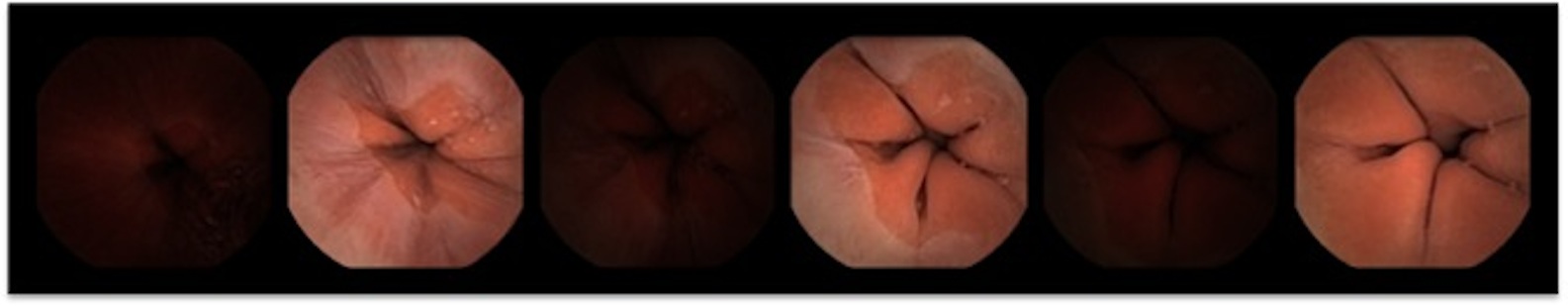
|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **SB24** | | **“SB2-like”** | | ***P* value** |
| **Frames** | **Mean ± SD** | **Frames** | **Mean ± SD** |
| Esophagus | 132 | 7.7 ± 9.0 | 91 | 6.5 ± 8.7 | NS |
| Stomach | 617 | 20.5 ± 34.2 | 403 | 13.4 ± 25.8 | NS |
| Small Bowel | 2227 | 11.5 ± 28.1 | 1490 | 8.1 ± 18.1 | NS |
| Colon | 249 | 14.6 ± 18.2 | 155 | 9.1 ± 12.4 | NS |
| Total | 3225 | 12.8 ± 15.2 | 2139 | 8.7 ± 15.6 | NS |

NS: Not significant; SD: Standard deviation.

**Figure 1 Sequence of the Z-line detected.** A: PillCam™ SB24; B: “SB2-like” capsule.

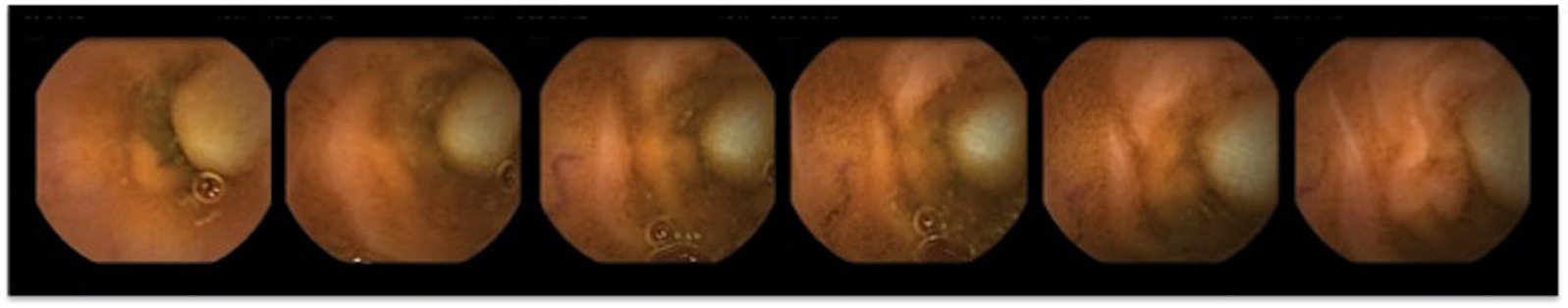


B



**Figure 2 Sequence of a submucosal lesion detected.** A: PillCam™ SB24 video; B:“SB2-like” video.

A



B

