Readjustment of Capsule Endoscopy Protocols to the COVID-19 Pandemic in a Portuguese Tertiary Center

João Correia, Ana Ponte, Catarina Gomes, Edgar Afecto, Maria Manuela Estevinho, Adélia Rodrigues, Rolando Pinho, João Carvalho

Department of Gastroenterology, Centro Hospitalar de Vila Nova de Gaia/Espinho EPE, Vila Nova de Gaia, Portugal

Cite this article as: Correia J, Ponte A, Gomes C, et al. Readjustment of capsule endoscopy protocols to the COVID-19 pandemic in a Portuguese tertiary center. *Turk J Gastroenterol.* 2022;33(7):570-575.

ABSTRACT

Background: *The prevention of severe acute respiratory syndrome corona virus 2 transmission implies several social distancing measures, imposing a change in the protocols of several hospital departments. Capsule endoscopy protocols changes were implemented and evaluated in a Portuguese tertiary center.*

Methods: *The authors compared pre-pandemic and peri-pandemic protocols, the latter favoring social distancing, used in MiroCam (IntroMedic, Seoul, Korea) and PillCam Crohn (Medtronic, Minneapolis, Minn, USA) capsule endoscopy, in a Gastroenterology Department of a tertiary center. All capsule endoscopy performed in outpatients between February 2018 and September 2020 was included. The authors compared significant lesions detection rate, completeness of procedure, adequate bowel preparation, complications rate, and patient satisfaction (through a brief phone call survey) among the protocols.*

Results: *This study included 70 MiroCam CE and 43 PillCam Crohn capsule endoscopy. No statistically significant differences concerning performance measures and patients satisfaction were found among the pre-pandemic protocol and the peri-pandemic protocol in MiroCam capsule endoscopy. Conversely, in PillCam Crohn capsule endoscopy, the rate of complete exams was significantly inferior in the peri-pandemic protocol (84.8% vs 50.0%, P = .036), with no other statistically significant differences in the remaining parameters.*

Conclusion: *The performance measures and patient satisfaction were similar among the protocols analyzed for MiroCam capsule endoscopy. Thus, the readjustment of this capsule endoscopy system, which favors a reduction in hospital stay, appears to be a good alternative to the former protocols in this pandemic era. In contrast, the rate of complete exams was significantly inferior in the adapted protocol to the pandemic era for PillCam Crohn capsule endoscopy, disfavoring its maintenance in the clinical practice.*

Keywords: *Capsule endoscopy, clinical protocol, COVID-19*

INTRODUCTION

The corona virus disease 2019 (COVID-19) pandemic has had a massive impact on several health departments worldwide. Concerning the Gastroenterology Departments, a decrease in diagnostic and therapeutic procedures was reported, due to health staff reallocation, preventive measures of severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) spread, and population lockdown.[1-3]

During the first pandemic peak in Europe, in which health services were overwhelmed by COVID-19 hospitalizations, several recommendations have been issued by different societies to prioritize endoscopic procedures.[4] The British Society of Gastroenterology, for instance, considered that during this phase capsule endoscopy (CE) should only be performed in cases of continuous or frequent small-bowel bleeding (overt or occult) in hospitalized patients or patients requiring frequent hospital admissions.[5]

However, CE is an endoscopic procedure with a very low risk of SARS-CoV-2 transmission. This exam generally requires 2 brief moments of direct contact between the patient and 1 healthcare worker: capsule placement and returning the equipment by the end of the procedure.[6]

Despite this minimal risk, readjustment of the procedure protocol in many Gastroenterology Departments after COVID-19 Pandemic breakout was needed, in order to provide a safe and efficient environment, similar to the telemedicine strategies adopted during the pandemic outbreak.[7]

This study aimed to compare pre-pandemic and peri-pandemic protocols, the latter favoring social distancing, used in MiroCam (IntroMedic, Seoul, Korea) and PillCam Crohn CE (Medtronic, Minneapolis, Minn, USA) performed in a Gastroenterology Department of a Portuguese tertiary center.

Corresponding author: ***João Paulo Laranjeira Correia****, e-mail:* ***joaopaulo_laranjeira@hotmail.com***
Received: ***July 18, 2021*** *Accepted:* ***September 20, 2021*** *Available Online Date:* ***April 11, 2022***

DOI: ***10.5152/tjg.2022.21574***

MATERIALS AND METHODS

All elective CE performed in outpatients between February 2018 and September 2020 from a tertiary center was included in this study. Two CE systems were addressed in this study and have been evaluated independently: MiroCam and PillCam Crohn. Data from pre-pandemic protocols was collected retrospectively, while data from peri-pandemic protocols was collected prospectively.

All CE studies were analyzed by a gastroenterologist with experience in the field. This study was approved by the local ethics committee.

MiroCam Protocols

This capsule system is used to study the small-bowel mucosa.

All patients took the same bowel cleansing procedure: clear liquids diet the day prior to the procedure and 2 L of polyethylene glycol solution the night before the exam. Patients are advised to walk during the procedure to optimize capsule progression. Four hours after capsule swallowing, patients were instructed to take a small meal.[8]

Before the COVID-19 pandemic, 2 protocols were used in this center, depending on patients' comorbidities and preference:

- Protocol A: Capsule endoscopy exclusively performed at the Gastroenterology department, with the supervision of a nurse. "Real-time" viewing was used to ensure the capsule reached the small-bowel and the colon. Cases of capsule persistence in the stomach would result in the administration of domperidone (1 hour after swallowing) or endoscopic placement of the capsule in the small-bowel (2 hours after swallowing).
- Protocol B: Capsule endoscopy partially performed at home after capsule swallowing and small-bowel visualization through "real-time". As in protocol A, cases of capsule persistence in the stomach would result in the administration of domperidone (1 hour after swallowing) or endoscopic placement of the capsule in the small-bowel (2 hours after swallowing). Twelve hours after capsule swallowing, the patient returned to the hospital to give back the equipment.

During the pandemic, in order to reduce the length of hospital stay, protocol C was created: Capsule endoscopy partially performed at home after capsule swallowing and prokinetic administration (domperidone 10 mg, taken orally), without performing "real-time" to confirm passage to the small-bowel. As in protocol B, 12 h after capsule swallowing, the patient returned to the hospital to return the equipment.

PillCam Crohn Protocols

This CE system is used to perform pan-enteric studies.

All patients took the same bowel cleansing procedure: clear liquids diet the day prior to the procedure, 1 L of polyethylene glycol solution the night before the procedure, and 1 L of polyethylene glycol solution the day of the procedure. After capsule swallowing, patients took 10 mg of oral domperidone. During the procedure, 4 numbers, associated to different steps, appear at the screen of the recorder: 1 – ingestion of 1 L of water and 30 mL of sodium phosphate; 2 – ingestion of 1 L of water and 15 mL of sodium phosphate; 3 – 10 mg of rectal bisacodyl; and 4 – taking a small meal. Patients are advised to walk during the procedure to optimize capsule progression.[8]

In the pre-pandemic protocol (protocol 1), the examination was entirely performed at the Gastroenterology department, with the supervision of a nurse.

In the peri-pandemic group (protocol 2), after capsule swallowing and verbal and written delivery of all the instructions, the patient was sent home and the rest of the exam was performed outside the hospital. Twelve hours after capsule swallowing, the patient returned to the hospital to give back the equipment.

Main Points

- *COVID-19 Pandemic has imposed several alterations in Gastroenterology Departments and their protocols, in order to prevent SARS-CoV-2 spread.*
- *This study evaluated pre and peri-pandemic capsule endoscopy protocols of 2 different capsule systems (Mirocam and PillCam Crohn).*
- *The performance measures of the peri-pandemic Mirocam protocol were not statistically different from the pre-pandemic protocols, favoring the implementation of the new protocol in the clinical practice: exam performed at home, after prokinetic administration, without performing "real-time" to confirm capsule passage to the small-bowel. This protocol reduced the patients' hospital stay significantly, a measure which can prevent SARS-CoV-2 spread.*
- *Peri-pandemic Pillcam Crohn protocol resulted in a significantly inferior number of complete exams, disfavoring its maintenance in the clinical practice.*

Performance Measures

In light of the 2019 European Society of Gastrointestinal Endoscopy (ESGE) guidelines on quality indicators in small-bowel CE,[9] the authors analyzed the following performance measures:

- Rate of exams with significant lesions
  - The following were considered significant lesions: P2 and P1 lesions according to the Saurin classification for intestinal bleeding; ulceration; erosions or strictures in the context of suspected/established Crohn's disease; small-bowel tumors and small-bowel polyps.[10]
- Rate of complete exams
  - MiroCam CE: An exam was considered complete if the capsule reached the cecum/colon or stoma bag (in patients who have had ileocolonic resection or other relevant surgery) during recording time.
  - PillCam Crohn CE: An exam was considered complete if the capsule was expelled during recording time.
- Rate of adequately prepared exams
  - MiroCam CE: Using Brotz preparation scale, an exam was considered adequately prepared if a quantitative index equal or higher than 7 and a qualitative evaluation of "Excellent" or "Good" were described.[11]
  - PillCam Crohn CE: An exam was considered adequately prepared if both small-bowel and colon were adequately visualized. For small-bowel visualization, the MiroCam definition was used; for colonic mucosa visualization, a subjective definition was used by the CE viewer (adequate or inadequate visualization).
- Rate of complications
  - Capsule retention was the only reported complication.

Patient Satisfaction

After the exam, a brief phone call interview was conducted to every patient who was included in this study. Two close-ended questions were asked to each patient, with the following possible answers:

- Question 1 (Q1): Do you consider the steps of this medical procedure simple?
  - Possible answers: yes or no.
- Question 2 (Q2): Concerning the place where the exam was held, what is your degree of satisfaction?
  - Possible answers: very satisfied (VS), moderately satisfied (MS), unsatisfied (US), or very unsatisfied (VU).

In order to simplify statistical analysis, the authors considered that the patient was satisfied if the answer for Q1 was "Yes" and the answer for Q2 was either "VS" or "MS." For different combinations of answers, the patient was considered not satisfied.

Statistical Analysis

Data were reported as median (interquartile, IQR) or mean (standard deviation, SD), when appropriate, for numerical variables and as absolute and relative frequencies for categorical variables.

For each CE system, the authors compared the performance measures and patient satisfaction between pre and peri-pandemic protocols.

Chi-square test or Fisher exact test, when appropriate, were used to compare categorical variables. Kruskal–Wallis test and student's t-test were used to compare age among protocols in MiroCam and PillCam Crohn CE, respectively.

The Statistical Package for Social Sciences (SPSS) version 25.0 software (IBM Corp.; Armonk, NY, USA) was used for statistical analysis. A *P* value less than .05 was considered as statistically significant.

RESULTS

MiroCam

This study included 70 MiroCam CE: 23 (32.9%) of protocol A, 21 (30%) of protocol B, and 26 (37.1%) of protocol C.

Median age was 62 years (IQR 29), and 46 (65.7%) of the patients were female.

When comparing demographical and clinical data among the 3 protocols, there were no statistically significant differences concerning mean age (*P* = .992), sex distribution (*P* = .294), and CE indication (*P* = .934) (Tables 1 and 2).

Overall, 39 (55.7%) of the exams performed provided the diagnosis of significant lesions, 68 (97.1%) of the exams were complete, 54 (77.1%) of the exams were adequately prepared, and only 1 (0.01%) capsule retention event was reported. Concerning patient satisfaction, 66 (94.3%) patients were satisfied with the procedure.

Table 1. Demographical Data of MiroCam Protocols

	Protocol A (n = 23)	Protocol B (n = 21)	Protocol C (n = 26)	*P*
Median age (IQR)	62 (36)	56 (29)	62 (27)	.992
Female sex, n (%)	18 (78.3)	12 (57.1)	16 (61.5)	.294

Table 2. Capsule Indications of MiroCam Protocols

	Protocol A (n = 23)	Protocol B (n = 21)	Protocol C (n=26)	*P*
Iron deficiency anemia, n (%)	12 (52.2)	14 (67.7)	15 (57.7)	
Obscure-overt gastrointestinal bleeding, n (%)	1 (4.3)	0 (0)	2 (7.7)	
Suspected Crohn's disease, n (%)	6 (26.1)	4 (19.0)	4 (15.4)	
Evaluation of Crohn's disease activity, n (%)	3 (13.0)	1 (4.8)	3 (11.5)	.934
Re-evaluation of erosive enteritis, n (%)	1 (4.3)	1 (4.8)	1 (3.8)	
Re-evaluation of subepitelial lesions, n (%)	0 (0)	0 (0)	1 (3.8)	
Unexplained weight loss, n (%)	0 (0)	1 (4.8)	0 (0)	

There were no statistically significant differences of the analyzed performance measures and the rate of satisfied patients, among protocol A, protocol B, and protocol C (Table 3).

PillCam Crohn

This study included 43 PillCam Crohn CE: 33 (76.7%) of protocol 1 and 10 (23.3%) of protocol 2. The mean age was 41.5 years (SD 14.2), and 26 (60.5%) of the patients were female.

When comparing demographical and clinical data between both protocols, there were no statistically significant differences concerning mean age (*P* = .397), sex distribution (*P* = .158), and CE indication (*P* = .600) (Tables 4 and 5).

Overall, 34 (79.1%) of the exams performed provided the diagnosis of significant lesions, 33 (76.7%) of the exams were complete, 41 (95.3%) of the exams were adequately prepared and no capsule retention events were reported. Concerning patient satisfaction, 39 (90.7%) patients were satisfied with the procedure.

When comparing both protocols, there were no statistically significant differences of significant lesions detection rate, rate of adequately prepared exams, complications rate, and rate of satisfied patients. However, protocol 2 had a significantly inferior rate of complete exams (84.8% vs 50.0%, *P* = .036) (Table 6).

DISCUSSION

In this observational study, 2 CE systems were analyzed and pre and peri-pandemic protocols were compared.

In order to standardize performance measures, reduce interobserver variability, and maximize its diagnostic yield, European Society of Gastrointestinal Endoscopy (ESGE) established the following minimum standards as markers of quality in small-bowel CE: significant lesions detection rate $\geq$ 50%, rate of complete exams $\geq$ 80%, rate of adequately prepared exams $\geq$ 95%, and complications (capsule retention) rate $<$ 2%.[9,12]

In the MiroCam analysis, the bowel cleansing measure was not achieved (77.1% of the exams were adequately

Table 3. Comparison of Performance Measures and Patient Satisfaction Among MiroCam Protocols

	Protocol A (n = 23)	Protocol B (n = 21)	Protocol C (n = 26)	*P*
Rate of detection of significant lesions, n (%)	12 (52.2)	10 (47.6)	17 (65.4)	.452
Rate of complete exams, n (%)	22 (95.7)	21 (100)	25 (96.2)	1.000
Rate of adequately prepared exams, n (%)	15 (65.2)	20 (90.5)	19 (73.1)	.150
Rate of complications, n (%)	0 (0)	0 (0)	1 (3.8)	1.000
Rate of satisfied patients, n (%)	22 (95.7)	20 (95.2)	24 (92.7)	1.000

Table 4. Demographical Data of PillCam Crohn Protocols

	Protocol 1 (n = 33)	Protocol 2 (n = 10)	*P*
Median age (IQR)	42.4 (14.9)	38.5 (11.9)	.397
Female sex, n (%)	22 (66.7)	4 (40.0)	.158

Table 5. Capsule Indications of PillCam Crohn Protocols

	Protocol 1 (n = 33)	Protocol 2 (n = 10)	*P*
Iron deficiency anemia, n (%)	3 (9.1)	1 (10.0)	
Suspected Crohn's disease, n (%)	25 (75.8)	6 (60.0)	.600
Evaluation of Crohn's disease activity, n (%)	5 (15.2)	3 (30.0)	

Table 6. Comparison of Performance Measures and Patient Satisfaction Between PillCam Crohn Protocols

	Protocol 1 (n = 33)	Protocol 2 (n = 10)	*P*
Rate of detection of significant lesions, n (%)	26 (78.8)	8 (80.0)	1.000
Rate of complete exams, n (%)	28 (84.8)	5 (50.0)	.036
Rate of adequately prepared exams, n (%)	32 (97.0)	9 (90.0)	.415
Rate of complications, n (%)	0 (0)	0 (0)	NA
Rate of satisfied patients, n (%)	29 (87.9)	10 (100)	.558

NA, not applicable.

prepared). Protocol B had a better result in this parameter; however, the authors found no statistically significant difference among the 3 protocols. Thus, optimization of bowel cleansing procedures and a better delivery of preprocedure instructions may be solutions to optimize this performance measure.

Previous studies suggested that "real-time" viewing allowed a higher rate of complete exams.[13] However, there was no difference concerning the completeness of procedure between protocol B (allowing the patient to perform the exam at home after small-bowel visualization through "real-time") and protocol C (allowing the patient to perform the exam at home after prokinetic administration, without performing "real-time"). This relevant finding suggests that capsule progression is optimized by routinely administering a prokinetic after its swallowing, without the need to perform "real-time" to ensure the capsule reached the small-bowel. This change in the protocol allows a reduction in the length of hospital stay, promoting social distancing.

As for PillCam Crohn CE, the minimum standards were achieved for all performance measures, except for the rate of complete exams (76.7%). In fact, in protocol 2 (the peri-pandemic protocol, in which the exam was partially performed at home) only 50% of the exams were complete. This may be related to a failure in following the provided instructions given by the nursing staff to achieve this goal (taking the boosters or walking during the procedure). In fact, a sedentary status during the exam is often associated with incomplete CE.[14,15]

This study has several strong points. Firstly, data after the pandemic outbreak was collected prospectively. Secondly, 2 CE systems were analyzed in separate, allowing a more precise analysis. Thirdly, in both CE systems there were no statistically significant differences among the analyzed protocols concerning age, sex distribution and CE indications, eliminating potential selection bias. Fourthly, to our knowledge, this is the first original study that compares different CE protocols before and during the pandemic. Fifthly, patient satisfaction was analyzed in this study, allowing a humanization of health services, which is currently more difficult due to the obstacles imposed by the COVID-19 disease.

This study has however some limitations. Firstly, data prior to the pandemic was collected retrospectively. Secondly, the number of patients included in this study is low, especially in the PillCam Crohn CE, which is explained by the fact that this is an unicentric study that has been carried

during a time in which the number of diagnostic procedures diminished significantly. This, however, could have been overcome by a prolongation of the study. Thirdly, a subjective definition of colon cleansing was used in PillCam Crohn CE, without resorting to an objective and validated scale.[16] Fourthly, phone interviews were all carried after the pandemic outbreak, which means that some surveys were taken more than a year apart from the procedure, imposing an important bias on this analyzed parameter.

CONCLUSION

Concerning MiroCam CE, the performance measures and patient satisfaction were similar among the 3 protocols. Thus, the readjustment of MiroCam CE (Protocol C), which favors a reduction in hospital stay (since it does not resort to "real-time") appears to be a good alternative to the former protocols in this pandemic era.

As for PillCam Crohn CE, although most of the performance measures and patient satisfaction were similar between both protocols, the rate of complete exams was significantly inferior in the protocol adapted to the pandemic era (protocol 2), disfavoring its maintenance in the clinical practice.

Ethics Committee Approval: The study was reviewed and approved by the local ethics committee of the Centro Hospitalar Vila Nova de Gaia/Espinho.

Informed Consent: Verbal informed consent was obtained from the patients who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – J.C., A.P.; Design – J.C., A.P.; Supervision – A.P.; Resources – J.C.; Materials – A.P., A.R., R.P.; Data Collection and/or Processing – C.G., E.A., M.M.E.; Analysis and/or Interpretation – J.C., A.P., M.M.E.; Literature Search – J.C.; Writing Manuscript – J.C.; Critical Review – A.P.

Declaration of Interests: The authors have no conflict of interest to declare.

Funding: The authors declared that this study has received no financial support.

REFERENCES

1. *Crespo J, Fernández Carrillo C, Iruzubieta P, et al. Massive impact of coronavirus disease 2019 pandemic on gastroenterology and hepatology departments and doctors in Spain. J Gastroenterol Hepatol. 2021;36(6):1627-1633.* [CrossRef]
2. *Damm M, Garbe J, Eisenmann S, et al. Gastrointestinale Endoskopie in Zeiten der COVID-19-Pandemie: Umsetzung von Empfehlungen und Erwartungen für die Zukunft. [Challenges of the COVID-19 pandemic in gastrointestinal endoscopy: expectations and implementation of recommendations]. Z Gastroenterol. 2020;58(11):1074-1080.* [CrossRef]
3. *Koulaouzidis G, Charisopoulou D, Koulaouzidis A. Collateral casualties of COVID-19. J Am Coll Cardiol. 2021;77(20):2621-2622.* [CrossRef]
4. *Koulaouzidis A, Marlicz W, Wenzek H, Koulaouzidis G, Eliakim R, Toth E. Returning to digestive endoscopy normality will be slow and must include novelty and telemedicine. Dig Liver Dis. 2020;52(10):1099-1101.* [CrossRef]
5. *Rees CJ, East JE, Oppong K, et al. Restarting gastrointestinal endoscopy in the deceleration and early recovery phases of COVID-19 pandemic: guidance from the British Society of Gastroenterology. Clin Med. 2020;20(4):352-358.* [CrossRef]
6. *MacLeod C, Wilson P, Watson AJM. Colon capsule endoscopy: an innovative method for detecting colorectal pathology during the COVID-19 pandemic? Colorectal Dis. 2020;22(6):621-624.* [CrossRef]
7. *Koulaouzidis G, Marlicz W, Koulaouzidis A. Telemedicine in the time of COVID-19: better late than never. Am J Gastroenterol. 2021;116(5):1088-1089.* [CrossRef]
8. *Rondonotti E, Spada C, Adler S, et al. Small-bowel capsule endoscopy and device-assisted enteroscopy for diagnosis and treatment of small-bowel disorders: European Society of Gastrointestinal Endoscopy (ESGE) Technical Review. Endoscopy. 2018;50(4):423-446.* [CrossRef]
9. *Spada C, McNamara D, Despott EJ, et al. Performance measures for small-bowel endoscopy: a European Society of Gastrointestinal Endoscopy (ESGE) Quality Improvement Initiative. U Eur Gastroenterol J. 2019;7(5):614-641.* [CrossRef]
10. *Leenhardt R, Koulaouzidis A, McNamara D, et al. A guide for assessing the clinical relevance of findings in small bowel capsule endoscopy: analysis of 8064 answers of international experts to an illustrated script questionnaire. Clin Res Hepatol Gastroenterol. 2021;45(6):101637.* [CrossRef]
11. *Brotz C, Nandi N, Conn M, et al. A validation study of 3 grading systems to evaluate small-bowel cleansing for wireless capsule endoscopy: a quantitative index, a qualitative evaluation, and an overall adequacy assessment. Gastrointest Endosc. 2009;69(2):262-270.e1.* [CrossRef]
12. *Lazaridis LD, Tziatzios G, Toth E, et al. Implementation of European Society of Gastrointestinal Endoscopy (ESGE) recommendations for small-bowel capsule endoscopy into clinical practice: results of an official ESGE survey. Endoscopy. 2021;53(9):970-980.* [CrossRef]
13. *Shiotani A, Honda K, Kawakami M, et al. Use of an external real-time image viewer coupled with prespecified actions enhanced the complete examinations for capsule endoscopy. J Gastroenterol Hepatol. 2011;26(8):1270-1274.* [CrossRef]
14. *Westerhof J, Weersma RK, Koornstra JJ. Risk factors for incomplete small-bowel capsule endoscopy. Gastrointest Endosc. 2009;69(1):74-80.* [CrossRef]
15. *Yazici C, Losurdo J, Brown MD, et al. Inpatient capsule endoscopy leads to frequent incomplete small bowel examinations. World J Gastroenterol. 2012;18(36):5051-5057.* [CrossRef]
16. *de Sousa Magalhães R, Arieira C, Boal Carvalho P, Rosa B, Moreira MJ, Cotter J. Colon Capsule CLEansing Assessment and Report (CC-CLEAR): a new approach for evaluation of the quality of bowel preparation in capsule colonoscopy. Gastrointest Endosc. 2021;93(1):212-223.* [CrossRef]