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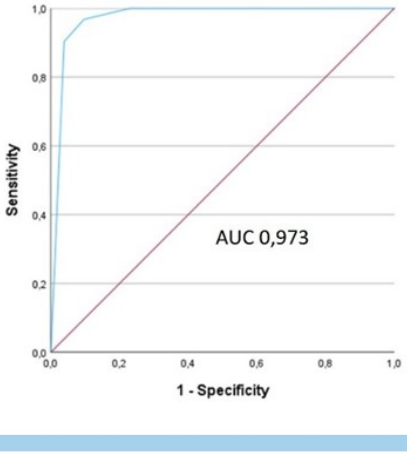
External Validation of a Capsule Endoscopy Scoring System (CESS-CD) for Early Crohn's Disease Diagnosis

An external validation of a capsule endoscopy scoring system (CESS-CD) for early Crohn's disease diagnosis was performed in 135 patients with suspected disease at a tertiary center in Portugal; the following performance metrics were observed.

Metric	Original Study (Ogino et al. 2025)	External Validation
Sensitivity	85.4%	96.8%
Specificity	80.0%	90.4%
Positive Predictive Value	70.8%	75.0%
Negative Predictive Value	90.9%	98.9%
Overall Accuracy	82.5%	91.9%
AUC (ROC Curve)	0.889 (derivation) / 0.925 (validation)	0.973

The CESS-CD score was calculated based on:

- Age ≤30 years (3 points)
- Linear erosion (4 points)
- Circumferential alignment (4 points)
- Cut-off value of 7 points.



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External validation of a Capsule Endoscopy Scoring System (CESS-CD) for early Crohn's disease diagnosis

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Financial Disclosure

Nothing to declare.

Abbreviations list

Small bowel capsule endoscopy (SBCE), Crohn's disease (CD), Capsule Endoscopy Scoring System for Crohn's Disease (CESS-CD), Receiver operating characteristic (ROC), Area under the curve (AUC), Positive predictive value (PPV), Negative predictive value (NPV), Inflammatory bowel disease (IBD), Computed tomography (CT), Magnetic resonance (MR), European Crohn's and Colitis Organisation (ECCO), Non-steroidal anti-inflammatory drug (NSAID), Interquartile range (IQR), International Committee of Medical Journal Editors (ICMJE), Statistical Package for the Social Sciences (SPSS),

Unidade Local de Saúde Gaia e Espinho (ULSGE), C-reactive protein (CRP), Simple Endoscopic Score for Crohn's Disease (SES-CD), Standard deviation (SD), Patient-reported outcomes 2 (PRO2).

Conflict of Interest

Nothing to declare.

Keywords: Crohn's disease. Small bowel capsule endoscopy. Inflammatory bowel disease. Endoscopic Scoring System. Early Crohn's diagnosis. Mucosal lesions.

Lay Summary

Crohn's disease is a chronic inflammation of the digestive tract that often begins in the small intestine. Detecting it early is critical to avoid complications and preserve intestinal function. Small bowel capsule endoscopy (SBCE) is a non-invasive procedure that allows doctors to view the small intestine, but interpreting the images can be subjective and variable. To improve this, a scoring system called CESS-CD was developed by Ogino et al. in 2025. It helps identify Crohn's disease based on three clear criteria seen on SBCE: younger age (≤30 years), linear erosions, and a specific pattern called circumferential alignment. However, this system had not yet been tested in a Western population. In this study, we tested the CESS-CD score in 135 patients undergoing SBCE in Portugal. We found that the score was highly accurate: patients with Crohn's disease had higher scores than those without. When the score was 7 or more (out of 11), it correctly identified Crohn's disease in over 96% of cases, and accurately ruled it out in over 98% of patients who didn't have it. This is the first independent validation of the CESS-CD in Europe. The score is simple, fast to apply, and may help standardize SBCE interpretation. If used more widely, it could improve early diagnosis and ensure timely treatment for patients with Crohn's disease.

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ABSTRACT

Background: Small bowel capsule endoscopy (SBCE) is widely recognized as a key diagnostic tool for Crohn's disease (CD). While several scores assess disease activity, a validated scoring system specifically designed for diagnosis was lacking. The Capsule Endoscopy Scoring System for Crohn's Disease (CESS-CD) was introduced in 2025 to address this gap in early CD diagnosis.

Methods: To externally validate the diagnostic performance and clinical utility of the CESS-CD in an independent, single-center cohort, clinical and SBCE data from 135 patients were retrospectively analyzed. The CESS-CD score was calculated based on age ≤30 years (3 points), presence of linear erosion (4 points), and circumferential alignment (4 points). Final diagnosis of CD was established by experienced gastroenterologists. Diagnostic performance was assessed via ROC curve analysis, with accuracy metrics calculated at the predefined cut-off of ≥7 points. Group differences were evaluated using the Mann–Whitney U test.

Results: The CESS-CD showed excellent diagnostic discrimination, with an AUC of 0.973 (vs. 0.925 in the original study). At the 7-point cut-off, sensitivity was 96.8% (vs. 83.3%), specificity 90.4% (vs. 80.0%), PPV 75.0% (vs. 83.3%), NPV 98.9% (vs. 80.0%), and overall accuracy 91.9%. CESS-CD scores were significantly higher in patients with CD compared to those without ($p < 0.001$).

Conclusion: This external validation confirms the CESS-CD as a highly accurate and robust diagnostic tool for early CD. Its strong sensitivity, NPV, and discriminative ability support its integration into clinical practice to enhance diagnostic precision and guide timely management.

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Introduction

Crohn's disease (CD) is a chronic, progressive inflammatory condition of the gastrointestinal tract in which early diagnosis of small bowel involvement is critical to prevent complications and preserve intestinal function (1). Although small bowel capsule endoscopy (SBCE) is not the initial diagnostic modality of choice, its superior mucosal visualization, diagnostic yield and patient acceptance have made it an increasingly valuable tool in detecting early small bowel involvement, demonstrating a higher diagnostic yield in comparison to computed tomography enterography, and magnetic resonance enterography (2, 3). Although there are well established SBCE scores for monitoring CD, like the Lewis score (4), SBCE interpretation for CD diagnosis remains subjective and lacks standardized diagnostic criteria, limiting its reproducibility and impact in early-stage CD.

To address this limitation, Ogino et al. (5) recently developed the Capsule Endoscopy Scoring System for Crohn's Disease (CESS-CD), a diagnostic model that integrates patient age (≤30 years), linear erosions, and circumferential alignment of diminutive lesions observed on SBCE. The CESS-CD demonstrated excellent discriminative ability in both derivation and internal validation cohorts, supporting its potential utility in early CD diagnosis. However, no external validation of the score has yet been performed, and its diagnostic accuracy in real-world clinical settings remains unknown.

In this study, we aimed to externally validate the CESS-CD in an European population with an independent, single-center cohort of patients undergoing SBCE for suspected small bowel pathology. By comparing the diagnostic performance of the score against a gold standard composite diagnosis, including clinical, endoscopic, radiologic, and histological data (6), we sought to assess its reliability, generalizability, and clinical applicability. Confirming its diagnostic value across different patient populations could support broader implementation of the CESS-CD in early CD detection and contribute to improved diagnostic precision in SBCE interpretation.

Methods

This was a retrospective, single-center study conducted to externally validate the CESS-CD. The authors reviewed consecutive adult patients who underwent SBCE between July 2022 and January 2025 at a tertiary hospital center due to suspected small bowel CD. Inclusion criteria: age ≥18 years, complete SBCE study, and availability of clinical, laboratory, and histological data sufficient to establish a definitive diagnosis. Exclusion criteria included known CD prior to SBCE, incomplete capsule studies, and findings consistent with alternative diagnoses (e.g., celiac disease, infections, or neoplasia). As this was a retrospective validation study, no formal a-priori sample size or power calculation was performed. Instead, all consecutive eligible patients who met the predefined inclusion criteria during the study period were enrolled.This study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the Ethics Committee of Unidade Local de Saúde Vila Nova de Gaia e Espinho. All patient data were anonymized and handled in compliance with institutional and national data protection regulations.

All examinations were performed using the OMOM® HD video capsule (Jinshan Science and Technology, Yubei, China) and reviewed with the OMOM® Vue software at a frame rate up to 14 frames per second. All patients were instructed to discontinue non-steroidal anti-inflammatory drugs at least four weeks prior to the procedure. Bowel preparation consisted of 1 L of polyethylene glycol plus ascorbic acid administered after the capsule reached the duodenum, a protocol routinely used in our center to optimize small-bowel visualization (7).

The capsule endoscopy images were reviewed by two experienced readers who were blinded to the clinical data and the final diagnosis. Discrepancies between readers were resolved by consensus. The SBCE images were viewed at a maximum rate of 14 frames per second, and the small bowel images were divided into tertiles according to small bowel transit time, following the methodology of the original study. The CESS-CD was calculated for each patient as described by Ogino et al. The score includes three binary variables: age ≤30 years (3 points), presence of linear erosions (4

points), and presence of circumferential alignment of ≥3 diminutive mucosal lesions within a single small bowel segment (4 points). Each patient's total score ranged from 0 to 11 points, and the cut off for CD diagnosis was 7 points or more. Lesion classification followed the original definitions of Ogino et al. study, erosions were defined as mucosal breaks measuring less than 3 mm, whereas larger defects were classified as ulcers. Linear, longitudinal, or circular mucosal injuries were distinguished based on the minor axis of the lesion (< 3 mm). Erosions and small ulcers of any type were collectively considered diminutive lesions (5).

Clinical, laboratory, endoscopic, radiologic, and histologic data were systematically collected for all patients. Clinical activity was defined using the Patient-Reported Outcome 2 (PRO2) score, which incorporates abdominal pain and stool frequency over a seven-day period, activity is defined as an abdominal pain score greater than 1 or a stool frequency score greater than 3 . Endoscopic activity was assessed using the Simple Endoscopic Score for Crohn's Disease (SES-CD), with active disease defined as SES-CD >3, and histologic activity was determined by the presence of neutrophilic inflammation on ileocolonoscopic biopsies (10). Imaging activity was characterized by radiologic features of active inflammation on MR or CT enterography, such as bowel wall thickening, mural hyperenhancement, edema, increased T2 signal, or complications including fistulas or abscesses (11). Perianal disease was identified by the presence of fistulas, abscesses, ulcers, or stenosis.

The diagnosis of Crohn's disease was established according to ECCO consensus, integrating clinical symptoms, laboratory markers (CRP, fecal calprotectin), endoscopic and histopathological findings, and cross-sectional imaging (12). When conventional modalities were non-diagnostic, small-bowel capsule endoscopy was performed as an adjunct. Alternative causes of mucosal inflammation were systematically excluded. Clinicians responsible for the final diagnosis had access to the complete clinical work-up, including capsule endoscopy, but were blinded to the calculated CESS-CD score.

Descriptive statistics were used to characterize the study population. Continuous variables were compared between groups using the independent samples t-test, with variance homogeneity assessed via Levene's test, or the non-parametric Mann–Whitney U test when appropriate. Categorical variables were assessed using the Chi-square test or Fisher's exact test when expected cell counts were less than five. The diagnostic performance of the CESS-CD was assessed using Fisher's exact test (due to low expected frequencies in one cell of the 2×2 contingency table), receiver operating characteristic (ROC) curve analysis, with calculation of area under the curve (AUC), sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy at the predefined cut-off of ≥7 points. Normality of score distribution was assessed through visual inspection of histograms, which revealed non-normal distribution in the non-Crohn group; therefore, group comparisons were performed using the nonparametric Mann–Whitney U test. Statistical analyses were performed using IBM SPSS Statistics version 29.0.0, with significance defined as $p < 0.05$.

Results

A total of 135 patients undergoing small bowel capsule endoscopy (SBCE) for suspected small bowel pathology were included in the analysis.. Thirty-one patients (23.0%) received a final diagnosis of Crohn's disease (CD), while 104 (77.0%) were classified as non-CD. Baseline characteristics are summarized in Table 1. Significant differences between the Crohn's disease (CD) and non-Crohn's groups were observed in sex distribution (p=0.038) and White Blood Cell (WBC) counts (p=0.048). The CD group demonstrated a higher proportion of male patients (64.5%) compared to the non-Crohn's group (43.3%), and also had significantly elevated mean WBC counts (7.55 ± 2.06 $\times 10^9$/L vs. 6.71 ± 1.90 $\times 10^9$/L). Conversely, no statistically significant differences were found between the groups regarding age, other inflammatory markers (CRP and fecal calprotectin), endoscopic or radiologic evidence of inflammation, histological findings, perianal disease, or clinical activity. While CD patients exhibited a numerical trend toward higher levels of CRP and fecal calprotectin, and greater prevalence of

endoscopic and radiologic abnormalities, these differences did not reach statistical significance.Table 2 presents the variables used to calculate de CESS.CD.

Table 1. Baseline demographic, clinical, laboratory, endoscopic, histological, and radiologic characteristics of the study population, presented for the overall cohort and stratified by final diagnosis of Crohn's disease

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	All patients	Crohn's disease	Non-Crohn's	P value
Age, years (mean ± SD)	43 ± 15	44 ± 15	43 ± 15	0.658
Sex, (%) male	48.9	64.5	43.3	0.038
Sex, (%) female	51.1	35.5	56.7	0.038
Hemoglobin, g/dL (mean ± SD)	13.75 ± 1.67	13.61 ± 1.46	13.70 ± 1.75	0.909
CRP, mg/dL (mean ± SD)	0.69 ± 1.68	1.02 ± 2.76	0.58 ± 1.12	0.225
Fecal calprotectin, µg/g (mean ± SD)	440 ± 1123	755 ± 1386	329 ± 1008	0.123
White blood cells, $\times 10^9$/L (mean ± SD)	6.90 ± 1.98	7.55 ± 2.06	6.71 ± 1.90	0.048
Clinical activity (%)	17.6	20.7	16.9	0.220
Histology suggestive of IBD, (%)	13.8	16.1	10.3	0.150
Perianal disease, (%)	11.2	14.8	10.2	0.500
Colonoscopy with inflammatory activity, (%)	28.8	42.3	25.0	0.09
Family history of IBD, (%)	17.9	22.2	15.4	0.660
Radiological findings suggestive of CD, (%)	35.0	41.2	33.1	0.121

Continuous variables are expressed as mean ± standard deviation; categorical variables as percentages. CD: Crohn's disease, CRP: C-reactive protein, SD: Standard deviation.

Table 2. CESS-CD variables of the 135 patients included in the study. CD: Crohn's disease.

Variable	Category	n	%
Age Group	≤30 years	45	33.3%

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Variable	Category	n	%
	>30 years	90	66.7%
Final Diagnosis (CD)	Crohn's disease (CD)	31	23.0%
	No CD	104	77.0%
Linear Erosion on SBCE	Present	54	40.0%
	Absent	81	60.0%
Circumferential Alignment	Present	34	25.2%
	Absent	101	74.8%

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The median CESS-CD score was significantly higher in patients with confirmed CD (median: 8.0, IQR: 0) compared to those without (median: 1.5, IQR: 3), as determined by the Mann–Whitney U test ($U = 87.0$, $Z = –8.288$, $p < 0.001$).

Cross-tabulation analysis showed a significant association between CESS-CD positivity (≥7 points) and Crohn's disease diagnosis (Fisher's exact test, $p < 0.001$), supporting the diagnostic discriminative capacity of the score. The crosstab is present in Table 3.

Table 3: Cross-tabulation of CESS-CD result and final diagnosis of Crohn's disease

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	CESS-CD < 7	CESS-CD ≥ 7	Total
Crohn's Disease	1	30	31
No Crohn's Disease	94	10	104
Total	95	40	135

ROC curve analysis demonstrated excellent discriminative ability of the CESS-CD, with an area under the curve (AUC) of 0.973 (95% CI: 0.948–0.998), as shown in Figure 1. At the predefined cut-off of ≥7 points, the CESS-CD yielded a sensitivity of 96.8%, specificity of 90.4%, positive predictive value (PPV) of 75.0%, negative predictive value (NPV) of 98.9%, and overall diagnostic accuracy of 91.9%.

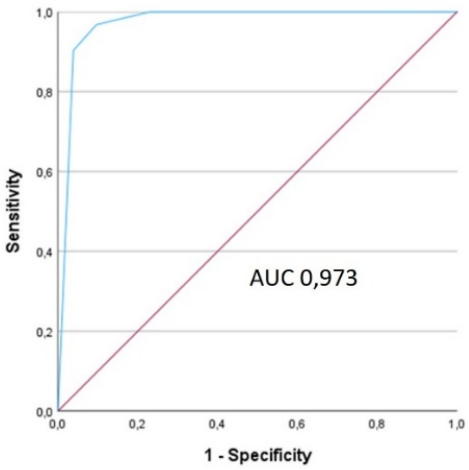

Fig. 1 ROC curve and Area Under the Curve of the Validation Study.

Compared to the original development study by Ogino et al., our cohort confirmed a good performance across all diagnostic metrics (see Table 4 for comparison).

Table 4. Comparison of diagnostic performance metrics for the CESS-CD score (cut-off ≥7 points) between the original development study (5) and the present external validation cohort.

Metric	Original Study (Ogino et al.)		External Validation
Sensitivity	85.4%		96.8%
Specificity	80.0%		90.4%
Positive Predictive Value	70.8%		75.0%
Negative Predictive Value	90.9%		98.9%
Overall Accuracy	82.5%		91.9%
AUC (ROC Curve)	0.889 (derivation) 0.925 (validation)		0.973

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Discussion

Early intervention and close disease monitoring are paramount in CD outcomes (13), early intervention with disease modifying agents can lead to a complete disease control and prevent irreversible complications of CD (14). Despite advances in imaging and endoscopy, diagnostic delay in CD remains a complex, multifactorial issue. Enhancing the diagnostic yield of tools already in clinical use may represent a practical and impactful strategy to mitigate this delay (15, 16).

The present study represents the first independent external validation of the Capsule Endoscopy Scoring System for Crohn's Disease (CESS-CD), a tool recently proposed to assist in the early diagnosis of small bowel CD using capsule endoscopy findings. In our cohort of 135 patients, the CESS-CD demonstrated excellent diagnostic performance. These findings support the score's generalizability and highlight its utility in real-world clinical settings where early diagnosis of CD remains a significant challenge.

Compared to the original development study by Ogino et al., our results show even stronger performance across key diagnostic metrics, including sensitivity (96.8% vs. 85.4%), specificity (90.4% vs. 80.0%), and negative predictive value (98.9% vs. 90.9%). These differences may reflect population heterogeneity, stricter exclusion of confounders such as NSAID use, or greater reader consistency in our cohort. Importantly, the improved NPV suggests the score is particularly well suited to rule out Crohn's disease in patients with low or intermediate pre-test probability, reinforcing its clinical relevance.

Our results also demonstrate that patients with CD had significantly higher CESS-CD scores than those without CD, as confirmed by a Mann–Whitney U test ($p < 0.001$). This adds to the evidence that the score effectively distinguishes between inflammatory and non-inflammatory small bowel lesions based on SBCE, a technique known for its high sensitivity but often limited by interpretative variability (17). The use of a structured score like CESS-CD may enhance consistency across readers and institutions.

Despite these promising findings, our study has several limitations. First, the absence of an a-priori sample size calculation; even though all consecutive eligible patients were included to reduce selection bias, larger prospective cohorts are warranted. This is a retrospective, single-center analysis, which may limit the generalizability of our results to broader or more diverse patient populations. Additionally, interobserver agreement between capsule readers was not formally assessed, and although image interpretation was conducted by experienced gastroenterologists, variability in lesion recognition could influence score calculation. Furthermore, the study did not evaluate the time interval between symptom onset and diagnosis, limiting our ability to directly correlate score performance with the clinical timeline of CD diagnosis.

Finally, as this study focused solely on diagnostic accuracy, we did not explore the impact of CESS-CD scoring on subsequent clinical management or long-term outcomes. Future multicenter prospective studies with larger and more heterogeneous cohorts, blinded independent image review, longitudinal follow-up, and standardized interobserver reliability assessment are warranted to confirm the reproducibility, prognostic value, and real-world clinical impact of CESS-CD implementation in routine practice.

In conclusion, this external validation study confirms the CESS-CD as a highly accurate, reproducible, and clinically useful scoring system for the early diagnosis of small bowel Crohn's disease. Its excellent diagnostic performance, particularly its high sensitivity and negative predictive value, supports its integration into routine capsule endoscopy interpretation to enhance diagnostic confidence and optimize patient management. Broader implementation of the CESS-CD could contribute to earlier detection, more timely treatment initiation, and ultimately improved long-term outcomes in patients with suspected Crohn's disease.

Financial Disclosure

Nothing to declare.

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Conflict of Interest

Nothing to declare.

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