

Title:

Artificial intelligence and capsule endoscopy

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Artificial intelligence and capsule endoscopy

Context	Primary Applications	Benefits
<p>Artificial intelligence (AI) is revolutionizing standard clinical practice.</p> <p>Capsule endoscopy (CE) positions itself as one of the most benefited areas.</p> <p>Interpreting a video CE may involve over 50,000 images. It is an error-prone complex process that requires experience and focus.</p> <p>Multiple AI algorithms are being developed to address small bowel (SB) conditions.</p>	<p>Mid-Gastrointestinal Bleeding: algorithms such as TOP100, SmartScan and ProScan improve lesion detection and location with > 90% sensitivity.</p> <p>Crohn's Disease: convolutional neural network (CNN) models allow high-precision ulcer identification and inflammation assessment.</p> <p>Tumor Lesions: deep learning (DL)-based algorithms detect polyps and neoplasms with > 90% specificity.</p>	<p>Reduced reading time</p> <p>Increased diagnostic accuracy</p> <p>Support for endoscopists in training, improving their learning curve</p> <p>Automatic assessment of bowel cleanliness</p> <p>Challenges and Future</p> <p>Lack of standardization and multicenter validation</p> <p>Medicolegal aspects of delegating diagnosis to AI</p>

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ABSTRACT

The advent of artificial intelligence (AI) is revolutionizing today's clinical practice, particularly in gastroenterology, where capsule endoscopy (CE) positions itself as one of the most impacted and benefited areas. Interpreting a video capsule endoscopy procedure, which may involve over 50,000 images per study, is an error-prone, complex process that demands experience and sustained focus.

AI, through deep learning models (DL) and convolutional neural networks (CNN), has optimized this reading procedure, demonstrating high sensitivity and specificity in the detection of lesions and providing diagnostic support in pathologies such as Crohn's disease and celiac disease, in addition to significantly reducing reading times. The use of AI as a first-reading tool stands out for its ability to select relevant images, speeding up the review of videos. Tools such as TOP100, already available in clinical practice, have proven effective in reducing reading times, facilitating prioritization in urgent scenarios. However, it faces significant challenges, such as the presence of false negatives. In its role as a second-reading tool, AI can confirm initial findings, detect unseen lesions, and serve as a training tool for physicians in training without compromising diagnostic accuracy.

In addition to its impact on reducing reading time, AI has shown potential in detecting intestinal lesions, locating them, and assessing intestinal cleanliness. Despite advances, its widespread adoption requires overcoming significant challenges such as lack of standardization and medico-legal issues. Future prospective, multicenter studies will help AI revolutionize CE interpretation, improving its accuracy and efficiency in clinical practice.

Keywords: Capsule endoscopy. Artificial intelligence. Small intestine. Convolutional neural networks.

INTRODUCTION

Recent technological advances in medicine have provided a wide array of tools that have transformed clinical practice. In this context, the use of artificial intelligence (AI) plays an increasingly relevant role in both the diagnosis and management of multiple conditions (1).

In the field of gastroenterology, particularly in endoscopy, capsule endoscopy (CE) is one of the techniques benefiting most from advances in AI. Currently, interpreting a CE study is a demanding and error-prone task, as it requires not only experience but also a high level of sustained concentration over long periods of time.

CE uses a device that allows to assess the entire small bowel (SB) (2) with a diagnostic yield that ranges from 55 % to 80 %, depending on indication (2). However, a significant rate of interpretation errors has been documented, ranging from 5.9 % for vascular lesions and 0,5 % for ulcers to 18.9 % for tumors (3,4). Most undetected lesion events result from human errors. A video CE study involves over 50,000 images and, on occasion, the condition of interest may be present in only one of them, which is greatly challenging. Presently, reading time ranges from 30 to 40 minutes (5).

In order to overcome the limitations of conventional reading (CR) and, especially, to optimize the time it takes, a number of AI-based visualization algorithms have been developed. These algorithms, integrated into various CE reading platforms, are designed to eliminate redundant frames. However, they have certain limitations, such as low sensitivity and a limited impact on reducing viewing time (6,7). According to the position paper of the European Society of Gastrointestinal Endoscopy (ESGE), the fundamental requirement for AI is that its performance must be comparable to that of expert endoscopists, without increasing—and preferably reducing—the operator's reading time (8).

This manuscript aims to review the advances in various AI models for CE applied to different GI pathologies.

HISTORY AND DEVELOPMENT OF ARTIFICIAL INTELLIGENCE

AI is defined as the scientific discipline dedicated to developing machines or software capable of mimicking human functions, such as learning and problem-solving, with the aim of performing tasks typical of human beings (9-11). To understand AI, it is essential to become familiar with certain key concepts:

Automated learning (AL), a branch of AI that allows machines to learn and improve their performance through data and algorithms without explicit programming following a repetitive cycle: problem posing, model training, evaluation and adjustment to optimize results (9,12).

Artificial neural networks (ANNs), another approach to AL, emulate the human brain using interconnected layers to process data, identify patterns, and perform specific tasks. Their adaptability makes them essential in advanced applications (9).

Another method in AL is the *support vector machine* (SVM), which classifies data by separating categories with a plane, being effective in identifying new patterns between different classes (9,13,14).

Deep learning (DL), based on multilayer ANNs, stands out in AL for its ability to improve with large volumes of data, being ideal for handling extensive sets of information (9,15). Among DL variants, *convolutional neural networks* (CNNs) stand out for their three-dimensional structure (width, height, and depth), optimized to extract and process image features more efficiently, achieving superior and faster performance compared to other models. Although its design and training require more time and data, CNNs have significantly boosted the development of AL, consolidating it as an essential subfield of AI (9,16).

Computer-assisted detection (CAD) combines knowledge from different disciplines. According to its objective, it is divided into paradigms such as aided detection (CADE), aided diagnosis (CADx) and aided quality assessment (CADq). CADE focuses on identifying abnormalities, while CADx characterizes these to predict diagnoses (16,17). On the other hand, CADq evaluates the quality of procedures, improving diagnostic accuracy and efficiency (17,18).

Figure 1, a hierarchical scheme illustrating AI modalities and their interrelationship within a clear conceptual framework is presented.

APPLICATIONS OF CE ARTIFICIAL INTELLIGENCE IN THE DIFFERENT INTESTINAL PATHOLOGIES

Mid-gastrointestinal bleeding

According to recent ESGE guidelines, CE is the first-line screening in patients with SB bleeding or mid-gastrointestinal bleeding (MGIB) following inconclusive gastroscopy and colonoscopy. MGIB is also the main indication for CE, and vascular malformations such as angiodysplasia constitute 50 % of the relevant findings in this context (19). Their identification is a challenge since these lesions usually appear in a small number of frames, therefore it is essential to develop advanced systems that allow their identification and localization quickly and accurately, thus improving clinical management.

Early AI approaches applied to CE focused on algorithms designed to identify bleeding by analyzing patterns related to color and texture (20). In 2003, as part of efforts to integrate CAD into CE, Medtronic developed the “Suspected Bleeding Indicator” (SBI) tool included in its reading software. This system aimed to help readers locate images with blood content by identifying frames with significant concentrations of red pixels and marking these segments for review. However, the system had a key limitation — its low specificity (20). Subsequently, the TOP100 tool appeared, currently incorporated into its CE video reading system (Software Rapid 9). This new software selects the most relevant 100 frames in the video, making it easier to identify significant lesions with the potential for high bleeding (P2). In a study carried out by Giordano et al., where 111 patients were included, the TOP100 showed a sensitivity of 90.48 %, specificity of 100 %, and a diagnostic accuracy of 92.79 % compared to CR. In the detection of active bleeding, the sensitivity of the tool reached 97 %-100 %, which demonstrates its effectiveness in detecting bleeding (21).

Soffer et al. (22), in their meta-analysis and systematic review reported promising results for CNNs, with a sensitivity of 98 % (95 % CI, 0.96-0.99) and a specificity of 99 % (95 % CI, 0.97-0.99) for the detection of gastrointestinal bleeding.

In a multicenter study for the development, training, and validation of an CNN-based model with CADe for the interpretation of CE videos, SmartScan Assisted Reading

(SSAR, already incorporated into the CE Omom HD clinical station) demonstrated a sensitivity of 95.9 % (95 % CI, 95.4 %-96.4 %) compared to Omom capsule CR, which achieved a sensitivity of 76.1 % (95 % CI, 75 %-77.3 %; $p = 0.001$) for the detection of up to 17 types of small bowel lesions according to CEST terminology, including vascular lesions. In addition, the use of SSAR significantly reduced reading times, with an average of 5.4 minutes (IQR, 4-6 minutes) versus 51.4 minutes (IQR, 43-58 minutes) for CR. These results underscore the potential of SSAR to optimize accuracy and efficiency in the interpretation of CE studies (23).

Mascarenhas-Saraiva et al. developed a model of CNN to classify SB lesions detected by CE according to their hemorrhagic potential. Trained on 53,555 images from PillCam SB3 and Omon HD, the model achieved 99 % accuracy, 88 % sensitivity, and 99 % specificity. Although it showed efficacy, its clinical use requires additional validation in full videos, as this system was trained with static images (24).

The company ANX Robotics[®] recently developed an AI tool that is available at the reading workstation of the NaviCam SB capsule. This CNN-based algorithm was evaluated by Ding et al. (25) in order to compare its diagnostic accuracy for various pathologies as an auxiliary to CR. Sensitivity and specificity for the detection of vascular lesions were 98.92 % and 100 %, respectively, while sensitivity decreased to 68.11 % ($p < 0.0001$) using CR with a specificity of 100 % ($p > 0.99$). The results showed that the overall reading time was significantly lower with CNN-based AI reading compared to CR (5.9 ± 2.23 min vs 96.6 ± 22.53 min vs; $p < 0.001$) (25,26).

In MGIB AI improves sensitivity, specificity, and read times, although clinical validation is needed in real-world scenarios (Table 1).

Crohn's disease

The role of CE in Crohn's disease (CD) has undergone a great evolution. Traditionally, magnetic resonance enterography (MRE) and computed tomography enterography (CTE) have been the most widely used tools to assess disease activity in these patients. However, CE is increasingly being adopted as a complementary examination of these, with a comparable diagnostic yield (27,28). CE allows the assessment of the inflammatory activity of the disease, its extension and mucosal healing using validated

scales such as the Lewis Index (LI) (29).

In 2020, Klang et al. developed a DL algorithm to analyze CE images. Based on 17,640 images of 49 CD patients and healthy subjects, the model achieved greater than 95 % accuracy in detecting ulcerative lesions in the SB, highlighting the potential of CE and AI in the diagnosis and monitoring of this disease (30).

Freitas et al. evaluated the concordance in CE reading of the TOP100 method and CR in patients with suspected or diagnosed CD. In a retrospective analysis of 115 patients, 64 (55.7 %) showed significant inflammatory activity ($IL \geq 135$) by CE. The results revealed a high concordance between both methods (Kappa: 0.83, $p < 0.001$), with an agreement of 89.6 %, especially in cases of moderate to severe inflammatory activity (Kappa: 0.92, $p < 0.001$). Therefore, although CR remains the gold standard, the TOP100 method proved to be an efficient tool for calculating the LI rapidly, particularly in patients with moderate to severe inflammation (31).

Barash et al. developed a CNN called ResNet to classify ulcer severity in patients with CD achieving an overall agreement with CR of 67 % and of 91 % for grade I to III ulcers, respectively. This demonstrates the high potential of AI (32) (Table 1).

Tumor lesions

Studies on CE standard interpretation and reading report higher missing rates for SB polyps and protruding lesions compared to ulcers and vascular lesions (33). Faced with these limitations, several research groups have developed innovative programs based on PC algorithms to optimize the detection of these lesions. In its early stages, most models were based on CAD. A significant example is the work of Li et al., who designed an automated system for the detection of lesions in the SB, based on the analysis of textures and color patterns. This system achieved promising results, with a specificity of 84 %, a sensitivity of 82 % and an overall accuracy of 83 % (34).

Yuan et al. developed a CAD method with the ability to identify polyps and other structures including the presence of bubbles and luminal material, reaching an accuracy of more than 95 %. This model is relevant, as it facilitates the elimination of luminal elements that may interfere with the proper evaluation of the images (35).

Saito et al. performed a retrospective evaluation of a novel CNN model designed for the automatic detection of protruding lesions. This AI was trained on 30,584 CE images obtained in 292 patients. Based on a CAD approach, the model aimed to identify polyps, tumors, masses, nodules, and venous structures. The system demonstrated an overall sensitivity of 90.7 % and a specificity of 79.8 %. In addition, it was able to correctly differentiate between the different types of lesions in a range of 42 % to 83 % of cases, with an average analysis time of 22.5 minutes. However, one of the main limitations observed was a high number of false negatives (36) (Table 1).

Celiac disease

Several studies have explored the use of AI in the classification of celiac disease by CE. Although it has great potential, its clinical applicability still requires further research. Among the main challenges are the similarity of mucosal atrophy with other pathologies and the need to combine multiple diagnostic criteria, including biopsies, to confirm the diagnosis of celiac disease. In the future, AI models could play a role as a preliminary screening tool, allowing the identification of patients in need of biopsies, and optimizing the diagnostic process (37).

Zhou et al. implemented a CNN based on GoogLeNet technology to assess SB involvement in patients with celiac disease, using CE videos generated with the PillCam SB2 system. The model achieved 100 % sensitivity and specificity. In addition, they introduced a quantitative measure called “assessment confidence” to determine the severity of injuries. Although the results are promising, limitations include the small number of patients evaluated and the use of an old-model capsule (38).

Wang et al., applied a CNN-based system using data obtained from 52 patients with celiac disease and 55 healthy controls, achieving the identification of lesions compatible with CD in CE images. The system achieved an accuracy of 95.9 %, a sensitivity of 97.2 %, and a specificity of 95.6 % (39).

In view of the current results we can say that there is potential to evaluate AI images that can help in the diagnosis of celiac disease, although more multicenter and prospective studies are needed (Table 1).

Panenteric capsule endoscopy

AI has begun to be applied to panenteric capsule endoscopy (PCE), which is a minimally invasive alternative to explore the colon in patients who refuse conventional colonoscopy or in those with contraindications to it. Saraiva et al. developed a CNN model using a database of 3,387,259 frames from 24 PCE studies to train and validate the model. The CNN detected protruding lesions with a sensitivity of 90.7 %, a specificity of 92.6 %, a positive predictive value of 79.2 %, and a negative predictive value of 96.9 %, with an area under the curve of 0.97. These results highlight the potential of AI to improve diagnostic accuracy and acceptance of PCE in colorectal neoplasm screening (40).

Using artificial intelligence as first and/or second reading method in capsule endoscopy

A major limitation of CE is the long reading time required for its assessment, leading to reader burnout and an increased likelihood of missing lesions. AI has its most important role in this area. In this sense, there is a controversy as to whether AI should be used as first and only reading method or as a complement to CR.

There is recent evidence that different AI systems offer a high diagnostic yield in the detection of lesions in the SB, positioning themselves as ideal tools to perform a CE first reading. This strategy significantly reduces reading time, as it selects only suspicious images for review (26). A retrospective study conducted by Aoki et al. (41), compared the time and effectiveness in the interpretation of CE videos in two situations: (A) readings performed exclusively by endoscopists and (B) readings performed by endoscopists after a preselection of images using CNN. The results showed that the average reading time was significantly lower in process B (3.1 minutes on average) compared to process A (12.2 minutes on average < 0.001). This finding demonstrates the feasibility of integrating AI-based diagnostic aids into daily clinical practice, substantially reducing the time it takes to read a CE procedure.

In this same study, the rate of detection of lesions by capsule readers in training was also analyzed compared to experts, after preselection of images by CNN, without observing significant differences between the two (94 % vs 100 %, $p = NS$). This result

suggests that, with the support of AI-based systems, endoscopists in training could play the role of primary readers without compromising diagnostic accuracy. This would free up experts to focus on other clinical activities, thereby optimizing time and resource management (41).

The application of TOP100 (Medtronic®) on the first reading, as well as the reduction of reading time, have been mentioned in different publications (31,21). Giordano et al. reinforce the relevance of TOP100 by showing a 91 % reduction in reading time for CE (23 minutes with CR vs. 1.9 minutes with TOP100; range: 1.7-2.1 minutes). This time saving is crucial in urgent contexts, such as visible SB bleeding, where speed in detecting lesions is essential to prioritize interventions. However, TOP100 showed limitations, especially in the detection of lesions with low bleeding potential (P1 according to Saurín's Classification (42), which generated a significant percentage of false negatives. This underlines the need for a conventional second reading in negative or doubtful cases, thus ensuring a complete diagnostic evaluation. Although TOP100 optimizes analysis time and improves prioritization in critical cases, it does not replace conventional reading, which remains indispensable to ensure diagnostic accuracy (21).

Regarding the use of AI as a second reading in CE, studies are limited at the moment. It is considered that it could play an important role in confirming or better characterizing lesions initially detected by the expert reader, as well as in identifying overlooked findings. In training contexts, AI as a second reading could improve diagnostic sensitivity and facilitate the training of novice readers by improving their ability to identify lesions in the SB. Important limitations remain, as well as addressing medicolegal issues related to the delegation of diagnostic procedures to automated systems. It is essential to carry out prospective studies that evaluate the clinical and economic impact of AI in daily practice, ensuring its integration as a complement in reading processes to optimize time, improve diagnostic quality, and maintain clinical accuracy (26).

Artificial intelligence systems for lesion location in capsule endoscopy

Some studies have developed algorithms capable of identifying specific SB segments and locating lesions with high accuracy. Dimas et al. presented an innovative approach based on visual odometry (VO) that uses CNN to estimate capsule movement. This model, which incorporates color analysis to improve accuracy, achieved an average localization error of 2.70 ± 1.62 cm in a robotic-assisted environment, significantly outperforming traditional geometric methods. These advances represent a promising step towards the in vivo application of VO, opening up new opportunities for more precise local treatments (43).

Assessing bowel cleanliness using artificial intelligence

Recently *Nam et al.* developed DL-based software to design a cleanliness scale in an automated manner. This system was built using the InceptionResNetV2 model, trained on 3,500 images classified into five levels of cleanliness based on mucosal visibility. Validated in 96 cases, the software showed a high correlation with clinical assessments conducted by experts and set a threshold for determining proper SB preparation. This advance allows for more objective and uniform evaluations, improving diagnostic quality (44).

CONCLUSION

AI has demonstrated a potential transformative impact on CE, optimizing diagnostic accuracy, reading time, and efficiency in the interpretation of studies. However, there are still significant challenges that hinder its adoption in clinical practice. Many studies have been conducted under controlled conditions, with retrospective and single-center designs, using selected images, which carries risks of overfitting and limits their applicability to real clinical scenarios.

An additional concern is the medicolegal implication of relying on AI systems to perform diagnostic procedures autonomously. Even when used as support tools in a first review, there is a risk that a large volume of images will not be examined by a human expert. To address these challenges, it is essential to develop robust evidence supporting the usefulness of AI in CE, demonstrating its cost-benefit ratio, its time-saving capacity, and its effectiveness in improving lesion detection. Overcoming these

challenges would allow AI to transform CE, offering significant benefits for patients and professionals, and consolidating itself as an indispensable tool in this field.

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Table 1. Summary of studies that used AI methods to facilitate assessment of video CE in different health conditions

Table 1.1

Author	Application	Year of publication	Type of AI	Study characteristics	Results
Mid-gastrointestinal bleeding					
Hassan et al., <i>Biomedicine</i> (20)	Mid-gastrointestinal bleeding	2015	SVM	32 videos: 1200 training images and 1720 test images to detect bleeding	Sensitivity: 99.41 %, Specificity: 98.95 %
Ding et al., <i>Gastroenterology</i> (25)	Mid-gastrointestinal bleeding	2019	CNN ResNet	Training 158,235 images from 1970 patients, validation performed in 5000 patients for lesion detection	Sensitivity per patient 99.88 % and per lesion 99.90 %
Soffer et al., <i>Gastrointestinal Endoscopy</i> (22)	Mid-gastrointestinal bleeding	2020	CNN	10 studies analyzed 22,738 images. Meta-analysis	Sensitivity 98 % (95 % CI, 0,96-0,99) and specificity 99 % (95 % CI, 0,97-0,99)
Mascarenhas Saraiva et al., <i>British Medical Journal</i> (24)	Mid-gastrointestinal bleeding	2021	CNN	Building of a model to assess hemorrhagic potential of lesions. 5793 studies with CE. A total of 53,555 images	Overall accuracy 99 %, with 88 % sensitivity and 99 % specificity
Xie et al., <i>JAMA</i> (23)	Gastrointestinal bleeding and other findings	2022	CNN Smart Scan	Model based on 2927 training studies with CE and validation with	Sensitivity 95,9 % (95 % CI, 95,4 %-96,4 %)



				2898 studies with CE for lesion detection	
Giordano et al., <i>Surgical Endoscopy</i> (21)	Open mid-gastrointestinal bleeding	2023	AL TOP100	Assessment of diagnostic yield with TOP100 vs CR in 111 patients.	Per-patient analysis, TOP100 showed sensitivity at 90.48 %, specificity at 100 % and diagnostic accuracy at 92.79 % P2. Active bleeding: sensitivity 100 %

Crohn's disease					
Klang et al., <i>Gastrointestinal Endoscopy</i> (30)	Crohn's disease	2020	AP	49 studies with CE	Diagnostic accuracy 95 %
Freistas et al., <i>Scandinavian Journal of Gastroenterology</i> (31)	Crohn's disease	2020	AA TOP100	CR vs TOP100 in 115 patients for LI calculation	Strong agreement ($k = 0.83$, $p < 0.001$) between both methods, with special concordance in moderate to severe activity
Barash et al., <i>Gastrointestinal Endoscopy</i> (32)	Crohn's disease	2020	RNC (ResNet)	To develop and validate a model for classifying ulcer severity. With 17,640 images (7,391 with ulcers) from	The model showed 67 % overall agreement with CR, and up to 91 % accuracy (AUC 0.958) in telling mild from severe ulcers, with



				49 patients	performance being lower for intermediate grades
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Tumor lesions and celiac disease					
				With 17,640 images (7,391 with ulcers) from 49 patients	
Li et al., <i>Journal of Medical Systems</i> (34)	Protruding and tumor lesions	2012	SVM	Model for the detection of gastrointestinal tumors. Studies from 10 patients (analysis of textures and color patterns)	Sensitivity 82 % and specificity 83 %
Yuan et al., <i>Medical Physics</i> (35)	Protruding and tumor lesions	2017	CAD	Model for the identification of polyps, protruding lesions and their differentiation from other luminal structures. 1000 images of polyps and 3000 of normal mucosa.	Diagnostic accuracy 95 %
Saito et al., <i>Gastrointestinal Endoscopy</i> (36)	Protruding and tumor lesions	2020	CNN	Model for the identification and classification of luminal lesions. 30584 lesions were involved	Overall sensitivity 94.4 %
Zhou et al., <i>Computers in Biology and Medicine</i> (38)	Celiac disease	2017	CNN GoogLeN et	Identification of presence and mucosal involvement	Sensitivity and specificity 100 %



				degree. Images from 6 control studies and 6 patients	
Wang et al., <i>Computer Methods and Programs in Biomedicine</i> (39)	Celiac disease	2020	CNN	Ability to detect mucosal lesions in patients with celiac disease. Model using 52 patients and 52 controls	Diagnostic accuracy 95.5 % Sensitivity 97.2 % and specificity 95.6 %

Artificial intelligence (AI); capsule endoscopy (CE); support vector machine (SVM); deep learning (DL); automated learning (AL); convolutional neural networks (CNN); conventional reading (CR); Lewis index (LI); support vector machine (SVM); computer-assisted detection (CAD); visual odometry (VO).

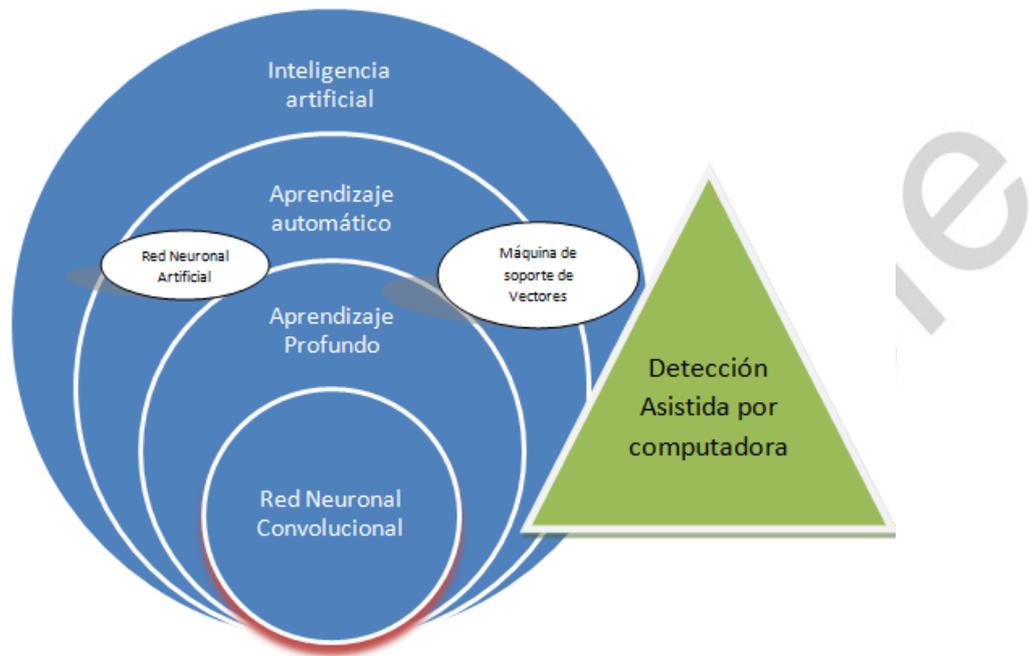


Figure 1. Schematic representation of the structure of artificial intelligence (adapted from Tziortziotis et al.) (9).

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