

**Title:**

**Advancements in biliopancreatic endoscopy: a comprehensive review of artificial intelligence in EUS and ERCP**

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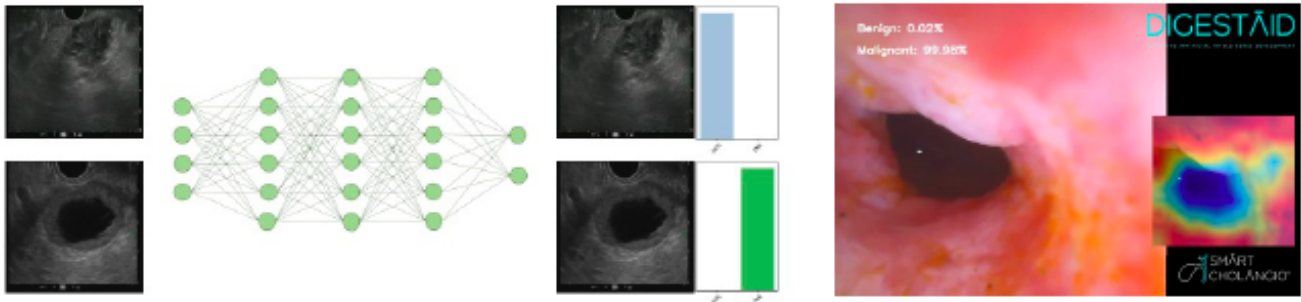
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## A COMPREHENSIVE REVIEW OF ARTIFICIAL INTELLIGENCE IN EUS AND ERCP



Example of an output generated by artificial intelligence with differentiation between different types of solid pancreatic lesions in an endoscopic ultrasound exam. The bars represent the probability estimated by the network ADC - pancreatic adenocarcinoma or TNE - pancreatic neuroendocrine tumor. In the right case in a biliary stricture the software discriminates in real time between benign and malignant origin, while a heatmap highlights the areas with highest probability of malignancy (Source: Digestaid).

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## **Advancements in biliopancreatic endoscopy: a comprehensive review of artificial intelligence in EUS and ERCP**

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### **ABSTRACT**

The development and implementation of artificial intelligence (AI), particularly deep learning (DL) models, has generated significant interest across various fields of gastroenterology. While research in luminal endoscopy has seen rapid translation to clinical practice with approved AI devices, its potential extends far beyond, offering promising benefits for biliopancreatic endoscopy like optical characterization of strictures during cholangioscopy or detection and classification of pancreatic lesions during diagnostic endoscopic ultrasound (EUS). This narrative review provides an up-to-date of the latest literature and available studies in this field. Serving as a comprehensive guide to the current landscape of AI in biliopancreatic endoscopy, emphasizing technological advancements, main applications, ethical considerations, and future directions for research and clinical implementation.

Keywords: Artificial intelligence. Endoscopic ultrasound. ERCP. Biliopancreatic endoscopy.

### **INTRODUCTION**

Artificial intelligence (AI) involves the use of computers and algorithms to simulate human-like decision-making and problem-solving processes <sup>1</sup>. It is widely considered a

revolutionary tool with the potential to transform medicine <sup>2</sup>. Imaging-based specialties have emerged as leaders in AI model development <sup>3</sup>. Gastroenterology, in particular, stands to benefit significantly from AI advancements, potentially leading to disruptive changes in clinical practice. Deep learning (DL), specifically convolutional neural networks (CNNs), are architectures inspired by the human visual cortex, excelling at image analysis <sup>4</sup>. Due to reduced pre-processing requirements and less reliance on prior knowledge, CNNs often outperform other DL models in lesion detection and differentiation <sup>5</sup>. Increased computational power and the development of sophisticated CNNs have driven an exponential growth in AI-related research within Gastroenterology, as is shown on recent reviews, highlighting the evolving applicability of AI in gastrointestinal endoscopy alongside relevant regulatory and ethical considerations for its general implementation in clinical practice<sup>6</sup>.

Upper endoscopy was one of the first areas to test the development of AI models <sup>7</sup>. In a recent meta-analysis, AI had comparable diagnostic accuracy to expert endoscopists in diagnosing Barrett esophagus and revealed a non-significant increase in the diagnostic accuracy of esophageal squamous cell carcinoma <sup>8</sup>. The role of AI in the diagnostic of early gastric cancer was also studied, with non-significant increase in diagnostic accuracy <sup>9</sup>.

AI-aided colonoscopy is an important study field, with focus in diagnosis of dysplastic adenomatous lesions. A recent systematic review and meta-analysis showed that AI-aided colonoscopy had a significant increase in adenoma detection rate (ADR) and adenomas detected per colonoscopy <sup>10</sup>. Interestingly, AI-aided colonoscopy was found to be more useful for endoscopists with lower ADR and shorter inspection time, while in experts it revealed a similar ADR. An important consideration is whether the increased ADR is accompanied by a detection of advanced adenomas, as the majority of the increased detection rate in individual studies was associated to an increase in detection of small adenomas and hyperplastic polyps <sup>11,12</sup>. Indeed, recent research focuses on the potential impact of AI on ADR within colorectal cancer screening programs, where it could play a significant role <sup>13</sup>.

In capsule endoscopy (CE), the development of DL models holds disruptive potential, addressing its inherent challenges. The process is not only time-consuming, but it also

susceptible to fatigue and errors (missed frames may lead to missed lesions)<sup>14</sup>. There are published complex CNN that can automatically detect multiple clinically relevant lesions with high diagnostic yield, and some are even capable of predicting their bleeding potential<sup>15-18</sup>. The scientific progress in this field has advanced from detecting lesions in the small bowel to encompassing both the small bowel and colon, while the ultimately goal is to extend this assessment to a comprehensive endoscopic approach<sup>19</sup>. While further prospective and multicentric studies are necessary, AI-enhanced CE may have a transformative impact in medical practice. This could improve its cost-effectiveness, broaden the current CE indications (e.g. CE after negative upper endoscopy, in patients presenting with upper bleeding) and even change the current paradigm to include endoscopic oncological screening for GI cancers<sup>20</sup>.

Beyond significantly reducing procedure interpretation time, the use of AI algorithms can play a crucial role in other gastroenterology procedures that involve a steep learning curve and suboptimal diagnostic accuracy with high inter-observer variability. This applies to specialized areas within gastroenterology, such as evaluating biliary stenosis in cholangioscopy, detecting/differentiating dysplastic precursor lesions in anoscopy and assessing EUS pancreatic lesions<sup>21-24</sup>. In these cases, the use of DL in real-life clinical setting would not only help the physician in the decision process, but also indicate the most likely location of the lesion, guiding the biopsy/treatment process. Although the current treatment paradigm of these lesions still demands histopathological assessment and confirmation, the prospective validation of these technological tools could lead to remarkable changes, perhaps even considering the omission of biopsies. This gains significance, particularly as multimodal AI technologies progress, encompassing both image data and other personal health records, assuming that computational processing power will keep pace with this technological advancement. This review offers a state-of-the-art examination of current research and advancements in AI-assisted biliopancreatic endoscopy.

Initial studies exploring its use in ERCP, EUS and cholangioscopy have shown promising results in identifying key anatomical landmarks during these procedures, as well as differentiating pathologies such as pancreatic cancer, autoimmune pancreatitis,

pancreatic cystic lesions, and biliary strictures.

## **ARTIFICIAL INTELLIGENCE ASSISTED EUS**

EUS is a valuable diagnostic tool used in a variety of clinical applications, including differentiating benign and malignant pancreaticobiliary disorders, staging gastrointestinal (GI) tract tumors, evaluating subepithelial lesions (SELs), and obtaining diagnostic tissue samples<sup>25</sup>. Compared to other endoscopic imaging modalities, fewer studies have investigated the use of AI for EUS image analysis. This can be attributed to several key challenges. Firstly, obtaining EUS images of targets with confirmed histological diagnoses presents greater difficulty than in luminal endoscopic techniques, where biopsies are more readily acquired. Secondly, the lower prevalence of pancreatic diseases compared to upper GI or colonic lesions results in a smaller pool of available data for AI model development. Finally, EUS images possess inherently lower resolution and are susceptible to quality degradation from external factors such as movement artifacts by patient's breathing and heartbeats that require real-time corrections and registrations by the AI models to compensate for image jitter and shifting.

The application of AI to enhance the differential diagnosis of pancreatic lesions using EUS images represents a pivotal frontier in current research. Despite its established role in pancreatic lesion diagnosis, EUS faces challenges, including low specificity and operator dependence. AI-assisted EUS has the potential to address these limitations, with studies demonstrating improved diagnostic accuracy and reduced interobserver variability. Multiple studies utilizing support vector machines (SVM), principal component analysis, and neural networks have shown that AI algorithms achieve significantly higher sensitivity and specificity than traditional EUS<sup>26-28</sup>.

### **Pancreatic cancer**

Pancreatic cancer (PC) has a poor global five-year survival rate (12%) and early diagnosis is crucial, as it can significantly improve survival rates<sup>29</sup>. While traditional imaging techniques have limitations, EUS offers superior sensitivity for detecting small pancreatic lesions<sup>30,31</sup>. Recognizing this advantage, researchers are actively exploring



the application of Alin conjunction with EUS (EUS-AI) for PC detection<sup>32-34</sup>.

In a recent meta-analysis DL models demonstrated superior performance compared to conventional EUS diagnosis in PC detection, with a 95% sensitivity and 90% specificity, suggesting a strong potential to improve early detection of the disease<sup>33,35</sup>. Of particular concern is the accurate differentiation between PC and benign conditions like chronic pancreatitis (CP) and autoimmune pancreatitis (AIP)<sup>36</sup>. Tonozuka et al. developed a DL-based computer-assisted diagnosis system to detect PC. Using control images from patients with CP or normal pancreas, their system achieved exceptional performance with area under the curve (AUC) of 0.92 and 0.94 (validation and testing, respectively)<sup>26</sup>. Similarly, Zhu et al. employed an SVM predictive model built from EUS image parameters to differentiate between PC and CP. Their model demonstrated an average accuracy of 94.2%, with sensitivity and specificity of 96.3% and 93.4%, respectively. While promising, these studies highlight the need for external validation to confirm generalizability<sup>37</sup>. Marya et al. successfully employed an EUS-CNN model capable of differentiating AIP from other pancreatic conditions with promising results. Their model demonstrated a sensitivity of 90% and specificity of 78% when distinguishing AIP from all other conditions. Specificity increased to 87% when considering only AIP versus PC<sup>38</sup>. These findings are significant, especially in light of a recent meta-analysis highlighting the limitations of EUS-tissue acquisition in accurately diagnosing AIP<sup>39</sup>.

### **Pancreatic cystic lesions**

AI holds promise for the endosonographic diagnosis and characterization of pancreatic cystic lesions (PCLs), an area where traditional EUS faces challenges with low interobserver agreement, especially in distinguishing neoplastic from non-neoplastic PCLs with an accuracy ranging from 48-94%<sup>40</sup>. Several studies have investigated the application of AI, particularly CNNs, to classify PCLs. Nguon and colleagues highlighted the potential of AI in distinguishing between mucinous and serous cystic neoplasms, achieving an accuracy of approximately 83%, comparable to visual assessment by endoscopists. While this result is promising, the study's focus was limited to two specific types of cystic lesions<sup>41</sup>. One notable retrospective study using a dataset of

5505 EUS images demonstrated that a high-precision CNN algorithm could distinguish mucinous from non-mucinous cysts with remarkable accuracy (98.5%), sensitivity (98.3%) and specificity (98.9%), and an AUC of 1<sup>42</sup>. AI has also shown potential in predicting malignancy, such as in patients with pathologically confirmed intraductal papillary mucinous neoplasms (IPMNs). Here, the AI model achieved an impressive AUC of 0.91 for diagnosing malignant IPMNs, surpassing the diagnostic accuracy of human experts using pre-operative EUS<sup>43</sup>. Machicado et al. explored the potential of AI in combination with EUS-guided needle-based confocal laser endomicroscopy (EUS-nCLE) for advanced IPMN diagnosis and risk stratification. Compared to established guidelines, their AI-assisted approach demonstrated higher sensitivity and accuracy with comparable specificity<sup>44</sup>. These findings suggest that AI-assisted EUS holds significant potential to revolutionize PCL risk stratification, aiding clinical decision-making and guiding follow-up strategies.

Within the field of AI-Assisted EUS, studies have explored the integration of AI with various techniques, including elastography, contrast-enhanced harmonic EUS (CH-EUS), and the assessment of cytology and histology samples obtained via fine needle aspiration (FNA) or biopsy (FNB)<sup>45-48</sup>.

An early prospective trial investigated using EUS elastography images, converted to vector data, and analysed with simple neural networks. Despite a small sample size (necessitating 10-fold cross-validation), this achieved an AUC of 0.93 in classifying malignant tumors<sup>49</sup>. In 2012 a larger, multi-centre blinded study (258 patients) validated the approach, outperforming hue histogram analysis<sup>45</sup>.

Systems like CH-EUS MASTER use deep CNNs and Random Forest algorithms for real-time pancreatic mass diagnosis and biopsy guidance. It provides real-time mass identification/tracking, differentiates PC from CP using perfusion analysis, and by utilizing real-time feedback provided by the endoscopists throughout the procedure, the system aids in the selection of the most suitable type and size of puncture needle, offers guidance on the optimal location and evaluates the quality of the obtained sample. Consequently, this integration of AI technology has the potential to decrease the number of punctures necessary to acquire an adequate sample, enhance puncture precision, and mitigate the likelihood of complications<sup>50</sup>. Udristoiu et al. advanced



machine learning in this field by integrating a more complex approach, enabling the model to consider temporal data from contrast-enhanced imaging alongside other image types. Five image sets were extracted per EUS exam (grayscale, color Doppler, CH, elastography) and the results achieved a 96.4% specificity and 98.6% sensitivity overall<sup>51</sup>.

Advancements in rapid on-site evaluation (ROSE) aim to improve diagnostic yield and accuracy. Lin et al. developed an AI-ROSE model as a potential substitute for manual ROSE during EUS-FNA. While the model demonstrates promise, its current sensitivity (under 80%) indicates a need for refinement<sup>52</sup>. An ideal AI-ROSE system should not only identify malignancy but also accurately assess sample adequacy. To maximize practicality, potential solutions include smartphone-based algorithms for rapid analysis or telepathology options for remote cytopathologist expertise.

**Table 1.** Summary of studies on DL Assisted - Endoscopic Ultrasonography in Pancreatic Disease.

Field	Study	Patient Population (n)	Objective	AI model	Outcomes
Pancreatic Cancer	Saftoiu et al, 2012 <sup>45</sup>	PC (211); CP (47)	Differentiate cancer from benign masses	Multi-layered perceptron	Sensitivity = 87.59% Specificity = 82.94% AUC = 0.94
Pancreatic Cancer	Udristou et al, 2021 <sup>51</sup>	PC (30); CP (20); pNET (15)	Diagnose focal pancreatic mass	Convolutional neural network and long short-term memory	Sensitivity = 98.6%, Specificity = 97.4% AUC = 0.98

Pancreatic Cancer	Tonozuka et al, 2021 <sup>26</sup>	PC (76); CP (34); Control (29)	Differentiate pancreatic cancer from chronic pancreatitis and normal pancreas	Convolutional neural network and pseudo-colored heatmap	Sensitivity = 92.4% Specificity = 84.1% AUC = 0.94
Pancreatic Cancer	Kuwahara et al, 2023 <sup>36</sup>	PC (524) Non-Cancer Patients (170)	Differentiate pancreatic cancer from non -cancer pancreatic lesions	Deep convolutional generative adversarial network	Sensitivity = 94% Specificity = 82% AUC = 0.90
Pancreatic cystic lesions	Kurita et al, 2019 <sup>53</sup>	Mucinous cystic neoplasms (23); Serous Cystic Neoplasms (15); IPMN (30); Other cyst types (17)	Differentiate benign from malignant cyst	Multi-layered perceptron	Sensitivity = 95%, Specificity = 91.9% AUC = 0.96
Pancreatic cystic lesions	Kuwahara et al, 2019 <sup>43</sup>	Benign IPMN (27); Malignant IPMN (23)	Predict malignancy of IPMN	Convolutional neural network	Sensitivity = 95.7%, Specificity = 92.6% AUC = 0.98
Pancreatic cystic	Vilas-Boas et	Mucinous PCL (17); Non-	Differentiate mucinous and	Convolutional neural	Sensitivity = 98.3%,



lesions	al, 2022 <sup>42</sup>	mucinous PCL (11)	non- mucinous PCLs.	network	Specificity = 98.9% AUC = 1
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Pancreatic cystic lesions	Vilas- Boas et al, 2022 <sup>42</sup>			Convolutional neural network	
PC: <i>Pancreatic cancer</i> ; CP: <i>Chronic pancreatitis</i> ; pNET: <i>Pancreatic neuroendocrine tumor</i> ; IPMN: <i>Intraductal papillary mucinous neoplasm</i> , PCLs : <i>Pancreatic cystic lesion</i> .					

### Other scenarios

Initial applications of AI in EUS focused on pancreatic disorders, but recent studies explore its potential for gastrointestinal SELs diagnosis, particularly gastrointestinal stromal tumors (GISTs). A recent meta-analysis of seven studies (2431 patients) demonstrated that the EUS-AI model employing CNNs achieved superior sensitivity (0.92) and specificity (0.82) in detecting GISTs compared to conventional endoscopy. Additionally, the model exhibited potential in assessing the malignant risk of GISTs<sup>54</sup>.

AI presents practical solutions for optimizing EUS training. A major challenge for novice endoscopists is accurately identifying anatomical structures. Deep-learning systems like BP MASTER tackle this challenge with station classification, segmentation, and real-time EUS guidance. These tools substantially improve trainee accuracy in recognizing stations and interpreting images, potentially shortening the learning curve<sup>55,56</sup>.

### ARTIFICIAL INTELLIGENCE IN ERCP

One of the most challenging diagnoses in GI diseases are biliary strictures (BS). BS are defined as indetermined when cross-sectional imaging, as well as tissue sampling, are inconclusive or negative<sup>57</sup>, and this represents a challenging clinical scenario. Almost 20% of BSs are of indeterminate etiology at their presentation<sup>58</sup>.

Conventional sampling techniques, such as ERCP-guided brush cytology or forceps biopsies are limited by a low sensitivity (45% and 48.1%, respectively) and the combination of the two techniques can barely increase the sensitivity (59.4%)<sup>59</sup>. EUS-guided tissue acquisition can significantly improve the diagnosis and sampling of BS,

particularly those located in the distal bile duct. It should be strongly considered as part of a comprehensive BS workup. However, EUS has limitations when strictures are caused by intraductal vegetative lesions, when they are located in the biliary hilum, or if biliary stents are already present.

Digital single operator cholangioscopy (D-SOC) has gained popularity due to recent technological advances, its availability and its advantages, such as allowing the direct visualization of the BS and the surrounding mucosa, and performing targeted biopsies. D-SOC is a safe procedure and can be cost effective at initial ERCP in certain situations<sup>60</sup>. While D-SOC demonstrates high success in identifying BS through visual assessment, with sensitivity and specificity rates of 94% and 95% respectively, the accuracy of D-SOC-guided biopsies is lower<sup>61</sup>. Sensitivity in this context ranges from 74% to 80%, while specificity remains high at 98%<sup>62,63</sup>. This highlights that tissue sampling might not be as reliable for diagnosis as endoscopic direct visualization. Some visual findings have been statistically associated with malignancy, like the presence of neovascularization or dilated tortuous vessels, irregular or nodular biliary mucosa, tumors or masses, irregular surface with ulcerated, infiltrative, or friable appearance<sup>64,65</sup>. But to date, there is a suboptimal inter-observer agreement among experts for interpreting the visual impression of BS. Moreover, some high-risk features can be present in certain benign instances, such as primary sclerosing cholangitis, which can result in false-positive malignant diagnoses.

Given the aforementioned limitations in the diagnostic approach to BS, there has been an increasing interest in exploring the potential of AI to overcome them. AI can potentially impact BS diagnosis by providing categorization (i.e., discriminating malignant BS from non-malignant BS) as well as improving the morphologic classification that has scarcely been assessed. A handful of important studies have been published in the last two years evaluating the accuracy of CNN in BS. In 2022 Saraiva et al evaluated the performance of their CNN on distinguishing between benign and malignant BS. With a total of 11,855 images from 85 patients (9695 malignant strictures and 2160 benign findings), the model had an overall accuracy of 94.9%, sensitivity of 94.7%, specificity of 92.1%, and AUC of 0.988 in cross-validation analysis<sup>66</sup>. Several important publications emerged in this setting during 2023. One



such study by Marya et al. evaluated the accuracy of their CNN for classifying BS compared to traditional ERCP-based sampling techniques. By analyzing 2,388,439 still images from 154 patients, their CNN demonstrated an overall accuracy of 0.906 for CNN-based video analysis, significantly greater than brush cytology (0.625,  $p = 0.04$ ) or forceps biopsy sampling (0.609,  $p = 0.03$ ). Their occlusion block heatmap analysis demonstrated that the most frequent image feature for a malignant BS was the presence of frond-like mucosa/papillary projections<sup>67</sup>. Later, Carlos Robles-Medrand (CRM) et al developed a new cholangioscopy based CNN for recognizing neoplasia in indeterminate BS in pre-recorded videos and real-time D-SOC procedures, and compared the model with cholangioscopy experts and nonexperts using the CRM and Mendoza classifications. This model achieved significant accuracy values for neoplastic diagnosis, with a 90.5% sensitivity, 68.2% specificity, and 74.0% and 87.8% positive and negative predictive values, respectively, and outperformed the two nonexperts and one of two expert endoscopists<sup>21</sup>. Simultaneously, Zhang et al. proposed a different model (MBSDeiT) capable of automatically selecting qualified DSOC images with high accuracy (AUC of 0.963 - 0.973 across internal and external testing data sets) and subsequently identifying 92.3% of malignant BS in prospective videos. MBSDeiT outperformed both expert and novice endoscopists<sup>23</sup>.

Ultimately Saraiva et al, evaluated their CNN with 84,994 images from 129 D-SOC exams in two centers (Portugal and Spain). The model achieved an 82.9% overall accuracy, 83.5% sensitivity and 82.4% specificity, with an AUC and AUPRC of 0.92 and 0.93, respectively. This model additionally showed outstanding performance in detecting tumor vessels and papillary projections, with AUC values of 0.98 and 0.96, respectively<sup>24</sup>. AI-based on clinical biomarkers like alkaline phosphatase, intrahepatic bile duct diameter and total bile duct diameter, could also serve as an auxiliary for diagnosing malignant bile duct obstruction<sup>68</sup>.

AI has also been evaluated to evaluate different aspects of ERCP. A computer-assisted system using CasNet, a segmentation architecture of DL trained on 1381 cholangiogram images, showed effectively assessment and classification of the degree of technical difficulty in endoscopic stone extraction during ERCP<sup>69</sup>. Additionally, CNN-based models have been developed to predict the location and the difficulty of

cannulation of the ampulla <sup>70</sup>. Machine learning models have also been proposed to predict post ERCP pancreatitis probability and identify new clinical features relevant for the risk <sup>71</sup>.

**Table 2.** Main studies evaluating CNN-based DL for Biliary Strictures Diagnosis

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Author (year)	Patient Population (n)	Objective	Study characteristics	Main outcomes
Saraiva et al, (2022) <sup>66</sup>	85	Automatic detection of malignant BSs in DSOC images	Pilot validation study	Overall accuracy 94.9% sensitivity 94.7%, specificity of 92.1%, AUC 0.988 for differentiating malignant from benign BS.
Marya et al, (2023) <sup>67</sup>	154	Analyzing DSCO images in real-time to accurately classify biliary strictures	Multicenter validation study	CNN had greater accuracy for biliary stricture classification (0.906) than that of brush cytology (0.625, $P = 0.04$ ) or forceps biopsy sampling (0.609, $P = 0.03$ ).
Robles-Medrandá et al, (2023) <sup>21</sup>	<i>Phase 1</i> 48 <i>Phase 2</i> 116	Validation of a CNN model for identification of malignancy in indeterminate BS	International multicenter, Two-stage validation study	90.5% sensitivity, 68.2% specificity, and 74.0% / 87.8% PPV and NPV, respectively in distinguishing neoplastic lesions.
Zhang et al, (2023) <sup>23</sup>	150	Validation of a novel AI model to identify and predict malignant BS	Multicenter diagnostic study	MBSDeiT accurately identified 92.3% of malignant BS in prospective testing videos.
Saraiva et	129	Distinguishing	International	Sensitivity 83.5%,

## LIMITATIONS OF ARTIFICIAL INTELLIGENCE AND ETHICAL ISSUES

Employing AI-assisted advancements in gastroenterological techniques, which enable endoscopists to see more and beyond in order to make better decisions, requires careful consideration of precautions to ensure trustworthiness. Technological development should follow the FAIR data principles<sup>72</sup>. To maximize AI's potential in healthcare, it must be findable (with clear data labelling and unique patient identifiers), accessible (ensuring transparent data sources for verifying algorithm robustness), interoperable (compatible with various devices for wider use), and reusable (promoting the use of open-source frameworks and allowing datasets to be reused whenever they prove useful in addressing clinical challenges). In addition to complex data acquisition and standardization, privacy concerns arise as data is collected, requiring robust protection. Healthcare blockchain innovations may address this, offering decentralized and secure data frameworks<sup>73,74</sup>. Addressing inherent selection biases is also critical to ensure a transparent and transferable AI, achievable only through high-quality training data<sup>75</sup>.

Furthermore, there are two AI-related ethical challenges that should be considered. One concern is the “black-box” characteristic of these algorithms, implying that AI models can identify patterns (e.g. lesions) imperceptible by physicians<sup>76</sup>. Even though understanding how some medical interventions work remains a challenge (for example, how certain drugs improve a patient's outlook without a fully known mechanism), there's a stronger resistance to AI making decisions in medicine without any human involvement<sup>77</sup>. The second concern tends to arise as a consequence of the first one. If the AI model identifies a lesion that the physician disagrees with, and it turns out there was a lesion, should the doctor be held responsible? Conversely, if the machine fails to detect a lesion that later appears (e.g. false negative), who should be accountable: the doctor or the AI model development company? FDA is currently approving Computer-aided detection and diagnosis (CADe and CADx, respectively) systems as Software as a Medical Device (SaMD). SaMD clearance implies that such technology aids in detecting clinically relevant lesions, but does not make diagnosis,

with the ultimate responsibility lying with the physician <sup>78</sup>. In the current moment, there are three commercially approved technologies: Gi Genius<sup>®</sup> by Medtronic<sup>TM</sup>, SKOUT<sup>®</sup> by Iterative Health<sup>TM</sup>, Veritai<sup>®</sup> by Satisfai Health<sup>TM</sup>.

The development of AI models is crucial for enhancing the diagnostic capabilities of EUS. However to ensure widespread clinical use, AI models must work accurately across different EUS devices. A significant concern in the development of DL models is the existence of an imbalanced dataset that is not adapted to the population in which the technology will be used, limiting the external validity of the results.

The use of AI-based endoscopic imaging for the diagnosis of BS has several potential clinical benefits that include reducing tissue sampling techniques, resulting in fewer procedures and its associated costs and adverse events and also reducing the paradoxical gap between visual impression and histology. It can also have an academical benefit, providing expert and non-expert endoscopists of a second opinion on lesions suggestive of neoplasia, helping to obtain a targeted sample, and reducing the current suboptimal level of interobserver agreement.

While promising, robust clinical adoption of AI necessitates further development and rigorous external validation. Currently, a significant limitation is the reliance on relatively small datasets, hindering the ability of algorithms to generalize across diverse patient populations. Continued research utilizing larger, more comprehensive datasets is crucial for ensuring reliable performance. Understanding real-world benefits, addressing ethical considerations, adherence to FAIR data principles, and a focus on clinical validation hold the key to revolutionizing diagnostic accuracy, optimizing interventions, and ultimately improving patient outcomes. Despite these challenges, the potential of AI in this field remains undeniable.

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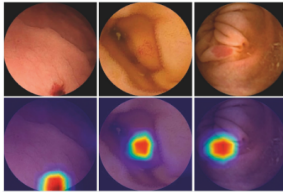


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## Main types of AI used in digestive endoscopy

### IMAGE RECOGNITION:

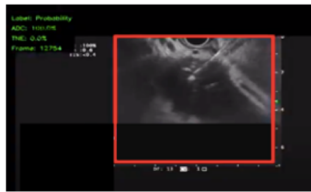
AI algorithms analyze endoscopic images to identify abnormalities.



e.g. AI-detects vascular lesion in stomach, small bowel or colon.

### HISTOLOGY PREDICTION:

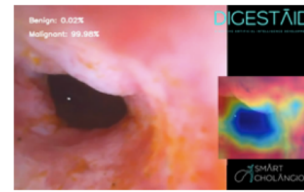
AI systems can predict histopathological features.



e.g. Probability of adenocarcinoma is shown in upper left quadrant.

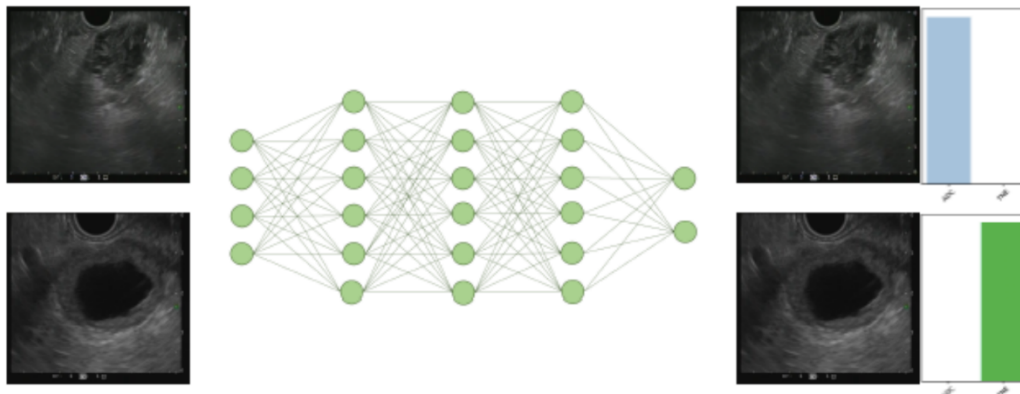
### REAL-TIME GUIDANCE:

AI can assist in real-time procedures and reduces exploration time.



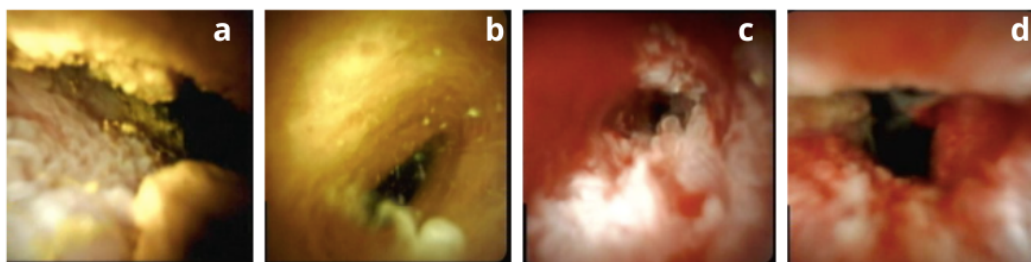
e.g. AI-assisted cholangioscopy for guided biopsies.

Fig. 1. Main types of AI used in digestive endoscopy.

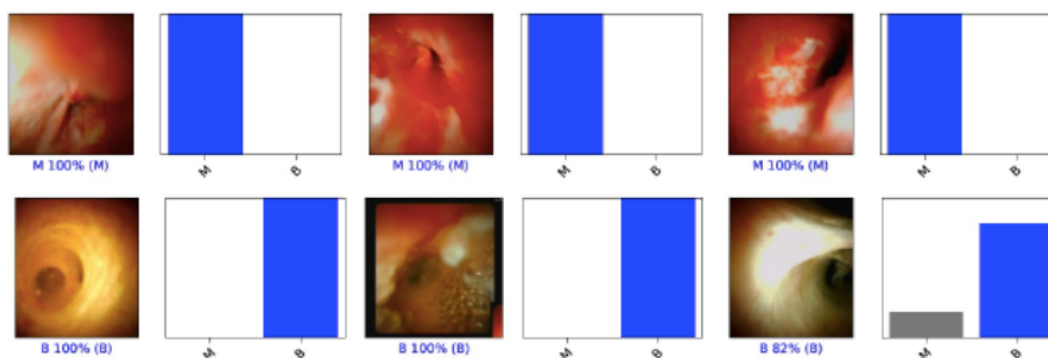


**Figure 2.** Output provided by artificial intelligence for distinguishing between various types of solid pancreatic lesions during an endoscopic ultrasound (EUS) examination. The bars depict the probabilities estimated by the network. ADC - pancreatic adenocarcinoma or TNE - pancreatic neuroendocrine tumor

Fig. 2. Output provided by artificial intelligence for distinguishing between various types of solid pancreatic lesions during an endoscopic ultrasound (EUS) examination.



**Figure 3.A.** Images of benign (a,b) and malignant (c,d) biliary stenosis in a digital single-operator cholangioscopy.



**Figure 3.B.** Output generated by the convolutional neural network for biliary stenosis in cholangioscopy. The bars represent the probability estimated by the model. M-Malignant, B-Benign.

Fig. 3. Images of biliary stenosis in digital single operator cholangioscopy (3A). Output of a convolutional neural network for differentiation between malignant and benign biliary stenosis (3B).