

Review

Risk Assessment and Cholangiocarcinoma: Diagnostic Management and Artificial Intelligence

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Citation: Granata, V.; Fusco, R.; De Muzio, F.; Cutolo, C.; Grassi, F.; Brunese, M.C.; Simonetti, I.; Catalano, O.; Gabelloni, M.; Pradella, S.; et al. Risk Assessment and Cholangiocarcinoma: Diagnostic Management and Artificial Intelligence. *Biology* **2023**, *12*, 213. <https://doi.org/10.3390/biology12020213>

Academic Editor: Georg Damm

Received: 19 December 2022

Revised: 21 January 2023

Accepted: 25 January 2023

Published: 29 January 2023



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Simple Summary: The only curative treatment for intrahepatic cholangiocarcinoma (iCCA) is surgical resection, and an early diagnosis is the most effective way to improve survival. In this context, Artificial Intelligence models may be able to evaluate higher-risk patients and thus improve diagnosis.

Abstract: Intrahepatic cholangiocarcinoma (iCCA) is the second most common primary liver tumor, with a median survival of only 13 months. Surgical resection remains the only curative therapy; however, at first detection, only one-third of patients are at an early enough stage for this approach to be effective, thus rendering early diagnosis as an efficient approach to improving survival. Therefore, the identification of higher-risk patients, whose risk is correlated with genetic and pre-cancerous conditions, and the employment of non-invasive-screening modalities would be appropriate. For several at-risk patients, such as those suffering from primary sclerosing cholangitis or fibropolycystic liver disease, the use of periodic (6–12 months) imaging of the liver by ultrasound (US), magnetic Resonance Imaging (MRI)/cholangiopancreatography (MRCP), or computed tomography (CT) in association with serum CA19-9 measurement has been proposed. For liver cirrhosis patients, it has been proposed that at-risk iCCA patients are monitored in a similar fashion to at-risk HCC patients. The possibility of using Artificial Intelligence models to evaluate higher-risk patients could favor the diagnosis of these entities, although more data are needed to support the practical utility of these applications in the field of screening. For these reasons, it would be appropriate to develop screening programs in the research protocols setting. In fact, the success of these programs requires patient compliance and multidisciplinary cooperation.

Keywords: cholangiocarcinoma; surveillance; risk assessment; artificial intelligence; radiomics

1. Background

Cancer is a critical obstacle to the improvement of quality of life, representing a leading cause of death worldwide [1]. The World Health Organization (WHO) report in 2021 [2] has shown that tumors are the first or second leading cause of death before the age of 70 years in 112 of 183 states and ranks third or fourth in a further 23 states.

Intrahepatic cholangiocarcinoma (iCCA) is the second most common primary liver tumor, with a median survival of only 13 months. Worldwide, many countries have suffered considerable escalation in mortality [3–5]. Surgical resection is the only curative treatment; however, at first diagnosis, only one-third of patients are at a sufficiently early stage such that this approach can be taken [6–10]. In addition, surgically treated iCCAs show a critical survival rate that ranges from 14% to 33% [11]. Locally advanced or metastatic tumors can be treated with several chemotherapeutic drugs. However, this approach offers few survival benefits [12]. Presently, a number of personalized treatments have been proposed as second-line therapies, although the choice should be correlated with the identification of a molecular profile [13]. Therefore, several ablative treatments have been assessed, although the real effects on survival should be proven [14–26].

According to their pathological features, iCCAs are classified as small- or large-duct types [27–33]. Regarding the small-duct subtype, affected patients present a mass-forming growth and chronic liver diseases are often comorbidities. Large-duct iCCA occurs as an infiltrative adenocarcinoma with a fibrotic stroma; this subtype is correlated with chronic cholangiopathies including primary sclerosing cholangitis and liver flukes. Mutations in KRAS and SMAD4 and the amplification of MDM2 are generally identified in large-duct iCCA; thus, S100P is a good marker for large-duct iCCA [27–33]. IDH1/2, BAP1, or FGFR2 are typical molecular features of small-duct iCCA, which are measured via C-reactive protein and N-cadherin in affected patients [27–33]. In addition to the well-known subtypes, unusual subtypes have also been identified, including a tubulocystic variant, a mucoepidermoid variant, an enteroblastic variant, and a cholangioblastic cholangiocarcinoma [27–33].

Small-duct iCCAs are associated with a better prognosis [27], which may be correlated with therapeutically significant IDH1-/2-mutations and FGFR2 gene fusions [28,29]. Correct patient stratification, according to molecular subgroups, could favor the development of personalized therapeutic strategies. In addition, an early diagnosis remains an effective way to improve overall survival, since a surgical approach is the only curative treatment. Therefore, the identification of higher-risk patients, whose risk is correlated with genetic and pre-cancerous conditions, and the employment of non-invasive-screening modalities would be appropriate. In this narrative review, we report an update on the risk features, screening guidelines, screening modalities, and the role of radiomics concerning patients at risk for iCCA.

2. Risk Factors

The precise features leading to the onset of iCCA are unknown, although several modifiable and non-modifiable risk factors are known [9,34–51]. With regard to the modifiable risk factors, these include alcohol consumption, dietary factors, smoking, hypertension, and obesity [9]. With regard to the non-modifiable risk factors, the following correlates are known: age, gender, type 2 diabetes mellitus (T2DM), genetic mutations (TERT, TP53, WNT or CTNNB1, KRAS, BRAF, SMAD4, FGFR2, IDH1 and IDH2, ARID1A, ARID2, PBRM1, BAP1, MLL3 or KMT2C, HDAC6, BRCA2, EGFR, and NTRKs), and clinical conditions such as Primary Sclerosing Cholangitis (PSC), biliary tree lithiasis, Cirrhosis, HBV and HCV, infectious Non Alcoholic Fatty Liver Disease (NAFLD), and Inflammatory Bowel Disease (IBD) [9]. In this scenario, it is clear that surveillance or preventive procedures would only

be useful for a limited portion of patients. Nevertheless, assessing the iCCA rate of at-risk patients is critical since an early diagnosis may imply a better prognosis.

3. Primary Sclerosing Cholangitis

Primary sclerosing cholangitis, a chronic cholestatic disease, is characterized by inflammation and fibrosis of the intrahepatic and/or extrahepatic bile ducts. This process, of unknown etiology, is responsible for the development of multifocal strictures and bile duct dilatations (Figure 1).



Figure 1. MRI of a 45-year-old patient affected by sclerosing cholangitis at baseline ((A): cholangiography sequence; (B): T2-weighted sequence in axial plane) and 6 years later after cholecystectomy ((C): cholangiography sequence; (D): T2-weighted sequence in axial plane). (A,C) 3D Magnetic resonance cholangiopancreatography and (B,D) T2 Axial images. The figures show progressive strictures and focal dilatations (white arrows) of intrahepatic biliary ducts over a period of 6 years.

PSC is strongly correlated with IBD (about 70–75% of patients), and the presence of both conditions in patients causes an increased risk of hepatobiliary and colorectal cancers [39–51]. In addition, PSC is the principal risk condition for CCA; thus, CCA remains a significant cause of mortality in patients with PSC [39–51]. The incidence of CCA in PSC varies between 0.6–1.5%, with a life-time risk of up to 20% [52]. Although CCA can be the first sign of previously undiagnosed PSC, about half of CCA-related PSC are diagnosed within the first year of PSC diagnosis [53,54]. The incidence of tumor development is the highest in patients with dominant strictures compared to small-duct PSC; in 76%, of cases the lesion is located in the peri-hilar region [39–51].

Today, since no surveillance strategy has been efficient with respect to the early detection of CCA, the clinical utility of surveillance is doubtful. The British Society of Gastroenterology's UK-PSC guidelines [43], compiled as a result of several study groups [53–58], do not suggest routine screening for CCA. However, the Mayo Clinic study group showed that annual surveillance, based on abdominal ultrasound (US), computed tomography (CT), or magnetic resonance imaging (MRI)/cholangiopancreatography (MRCP) plus CA19-9, is correlated with a higher 5-year iCCA-related survival compared to a non-surveillance group (21% vs. 8%) [59].

In addition, the Italian Clinical Practice Guidelines on Cholangiocarcinoma study group [9,10] proposed the use of regular (6–12 months) liver evaluation via US, MRI/MRCP, or CT combined with serum CA19-9 assessment for PSC patients with clinically stable disease.

A position statement from the International PSC Study Group (IPSCSG) [60] proposed MRI/MRCP as the first imaging tool applicable to PSC patients that assesses several prognostic features, such as parenchymal abnormalities, variable enhancement, liver stiffness, and functionality, by utilizing hepatobiliary specific contrast agents to evaluate the severity of liver fibrosis and the dilatation of the bile duct [61–83].

Regarding the reporting of radiological findings, considering the necessity of using a standardized lexicon [84–94], especially for the early detection of CCA, several studies have proposed the definition of terminologies and reporting standards to describe MRI/MRCP features during PSC patients' surveillance [39]. According to these studies [39], signs of CCA can be progression in the severity of previously detected strictures and/or an increasing upstream dilatation. In addition, contrast studies should be considered since any focal nodular thickening enhancement or focal thickening with associated portal vein narrowing should raise suspicion of CCA [39]. Functional studies based on diffusion-weighted imaging (DWI) could offer additional data; bile ducts can demonstrate diffusion restriction in the setting of inflammation and tumors [39,95–104]. For suspicious structures, an endoscopic retrograde cholangiopancreatography (ERCP) for biliary brushing should be considered [39].

Parenchymal atrophy and/or hypertrophy are non-specific features and can be seen in the setting of PSC or CCA [105–125]. The presence of liver metastases, lymphadenopathy, and peritoneal disease should be assessed [105–125].

4. Fibropolycystic Liver Disease

Fibropolycystic liver disease comprises several conditions, such as congenital hepatic fibrosis, choledocal cysts biliary, Caroli disease, and hamartomas. These afflictions have been proven to lead to a lifetime risk of CCA with an Odds Ratio (OR) similar to PSC [52,126,127].

Choledochal cysts (CCs), which are uncommon in Western populations (incidence of 1 to 100,000–150,000) and more frequent in some Asian populations (incidence of 1 in 1000), are congenital dilatations of the biliary tree, involving either extrahepatic (Figure 2) and/or intrahepatic biliary ducts [128–133].

CCs are usually categorized according to the Todani classification [134]: type I, the most common, is a solitary extrahepatic cyst; type II is an extrahepatic supraduodenal diverticulum (Figure 3); type III is an intraduodenal cyst (e.g., choledochocoele); type IV involves extrahepatic and intrahepatic cysts; and type V, referred to as Caroli's disease (Figure 4), comprises multiple intrahepatic cysts.

Although CC diagnosis can be accidental, during a liver assessment for other clinical indications, the diagnosis and characterization should be made with MRI/MRCP and ERCP [135].



Figure 2. MRI of a 64-year-old male patient with Choledochal cysts. (A,B): T2-weighted sequences in coronal plane; (C): 3D Magnetic resonance cholangiopancreatography. White arrows show dilations of the extrahepatic biliary tree.

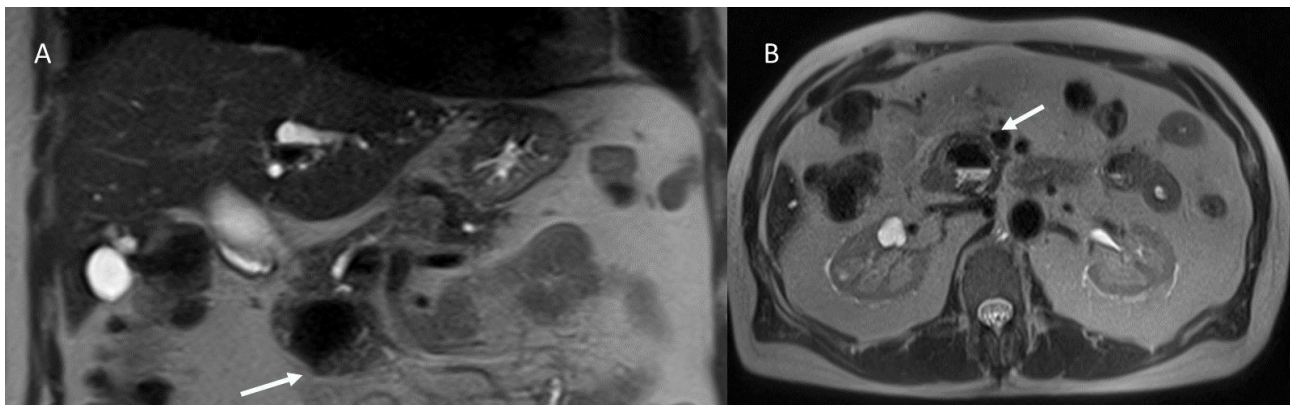


Figure 3. MRI of a 68-year-old male patient with Todani type II lesion. White arrows in coronal (A) and axial (B) T2-weighted sequences show an extrahepatic supraduodenal diverticulum.

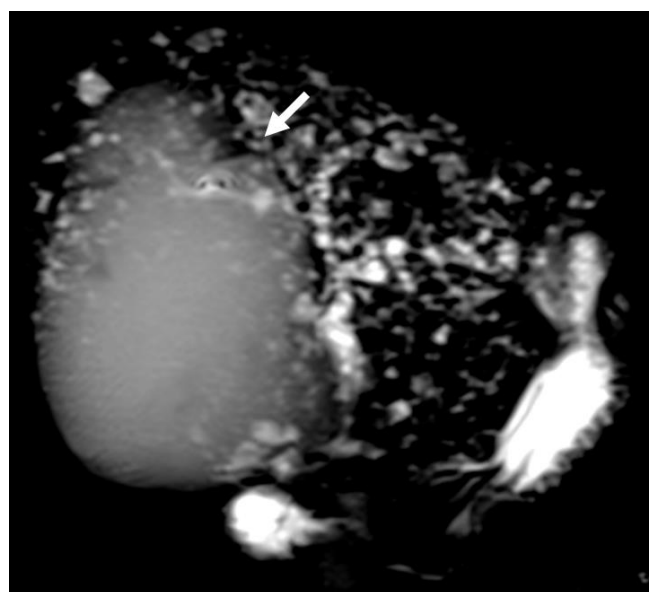


Figure 4. 2D Magnetic resonance cholangiopancreatography of 48-year-old female patient with Caroli's disease (white arrow shows cystic lesion).

Since malignancy risk increases with age, an early diagnosis and treatment leads to a more favorable outcome [135]. With regard to the different sub-types and malignancy risk, it has been demonstrated that among patients who develop biliary malignancy, around 68% occurred in type I, around 5% in type II, 1.6% in type III, 21% in type IV, and 6% in type V [134]. In addition, this risk increases if there is an anomalous pancreatic biliary junction (APBJ) [135], which is thought to be correlated with CCs.

Presently, treatment recommendations are based on Asian data, and there is no evidence that suggests an over-treatment of Western patients when Asian guidelines are followed. Therefore, current data suggest comparable efficacy of the treatment options between East and West [135].

With regard to surveillance, according to the Italian Clinical Practice Guidelines on Cholangiocarcinoma study group [9,10], these patients should be subjected to the same PSC patient strategy, comprising periodic (6–12 months) imaging evaluation using US, MRI/MRCP, or Computed tomography (CT) combined with serum CA19-9 measurement.

5. Liver Cirrhosis and Hepatitis

Liver cirrhosis is characterized by disseminated fibrosis and regenerative nodules due to chronic liver injury [136]. Cirrhosis can be the result of numerous insults, such as alcohol, NASH, autoimmune or viral hepatitis (B and C virus), and a number of toxic and metabolic reasons [136]. Whatever the cause of cirrhosis, several authors have assessed the iCCA risk in cirrhosis patients [39,40,137–142]. A meta-analysis that included 7 case-control studies with 339,608 patients demonstrated that cirrhosis has an OR of 22.9 when coupled with iCCA [143]. According to the European Network for the Study of Cholangiocarcinoma (ENSCCA) [144], among the 2234 analyzed patients, including 1243 (55.6%) with iCCA, 592 (26.5%) with pCCA, and 399 (17.9%) with distal (d)-CCA, 2.8% of them had hepatitis C virus, 4.6% had hepatitis B virus, 0.1% had a concomitant infection (mainly in the iCCA group), and 7.8% had cirrhosis (mainly in iCCA group).

In addition, although HBV and HCV are well known risk factors for cirrhosis, these viral agents have both been associated with approximately two-fold increases in CCA risk, independently of cirrhosis [145].

Although the relationship between HBV and iCCA is not as strong as for HCC, a meta-analysis and observational studies showed a four-fold to six-fold increase in risk [146–148]. Additionally, it is uncertain whether iCCA in HBV-infected patients is correlated with the virus itself or the development of cirrhosis. There are several histopathological differences between iCCAs in HBV-infected and uninfected patients that could support the idea of different biological factors and mechanisms that favor the onset of CCA. In fact, iCCA in infected HBV-patient is usually mass forming, with a higher percentage of capsule formation and lower percentage of lymphatic involvement [145]. Compared to HBV, HCV infection is more constantly correlated with a higher risk (Figure 5) [145].

Liver fluke infections are endemic in Korea, Thailand, China, Laos, Vietnam, and Cambodia. CCA is correlated with *Opisthorchis viverrini*, *Opisthorchis felinus*, and *Clonorchis sinensis* infection due to the consumption of raw or undercooked freshwater fish [149].

Human Immunodeficiency Virus (HIV) infection may increase the risk of iCCA [145]. HIV is known to be correlated with an increased risk of cholangitis via AIDS cholangiopathy or due to opportunistic infections [145].

With regard to obesity, metabolic syndrome, diabetes, NAFLD, smoking, alcohol, hepatolithiasis, and inflammatory disorders, since all these entities are responsible for chronic inflammation and cirrhosis, it was proposed that these patients should be monitored as is performed for patients with HCC [9,150].

The HCC-screening guidelines developed by the AASLD and the European Association for the Study of the Liver (EASL) and the Asian Pacific Association for the Study of the Liver (APASL) recommend surveillance for HCC in select high-risk populations with US alone (EASL), in concert with AFP (APASL), or with AFP as an option (AASLD),

using a surveillance interval of 6 months. Given its remarkable safety, accessibility, and cost-effectiveness, US is the main imaging tool for patients at high risk for HCC [150,151].

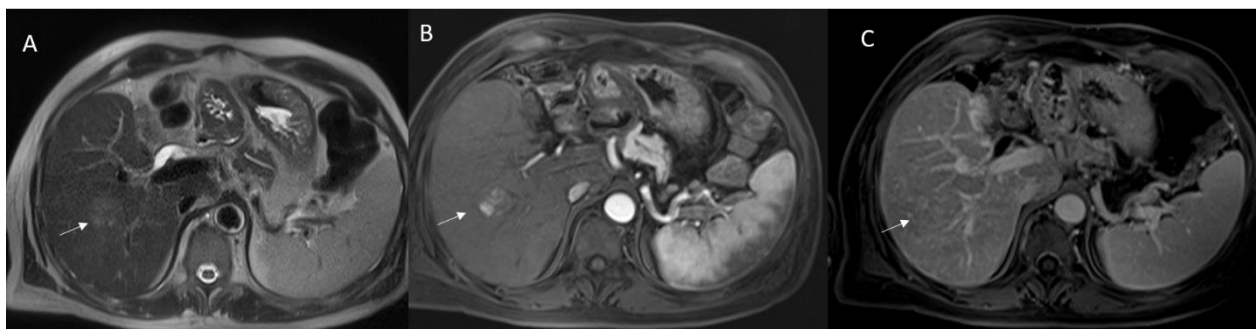


Figure 5. MRI of HCV 47-year-old patient with a case of intrahepatic cholangiocarcinoma. In T2-weighted sequence (A), the lesion (arrow) shows inhomogeneous signal, iso-hyperintense. During vascular assessment ((B): arterial phase; (C): portal phase), the lesion is characterized as LR-M (rim APHE (in (B), white arrow) and without washout (in (C), white arrow)). (B,C): gradient T1-weighted sequences (Volumetric interpolated breath-holding examination sequence), in axial plane in arterial and portal phases.

The American College of Radiology (ACR) proposed a standardized algorithm for screening and surveillance of high-risk patients using US (US-LI-RADS) [152–164]. The LI-RADS algorithm provides a standardized lexicon, diagnostic protocol, and a guide to assess several radiological patterns that can be reported to patients at risk for HCC. The system has been updated since the first edition in 2011, with the latest edition released in 2018 [164].

While in CT/ MRI, as in contrast-enhanced (CE) LI-RADS, each single observation is assigned to a category, for US LI-RADS, category assignment is performed in accordance with a full examination by utilizing observations of the main suspected tumors and includes three categories: US-1 negative, US-2 subthreshold, and US-3 positive. According to the assigned category, it has proposed several recommendations [164]:

For US-1, the patient should undergo routine surveillance consisting of a US examination every 6 months.

For the US-2 category, in which a tumor < 10 mm (or more) is measured, it is requested that the nodules are analyzed via US surveillance for up to 2 years with short-intervals (every 3–6-months).

For US-3 positive assignment, further characterization (HCC vs. iCCA) with multi-phase contrast studies is suggested [164].

6. Precursors Lesions of Cholangiocarcinoma

CCA Carcinogenesis is a multifarious process starting with transformed biliary epithelial cells or originating from stem/progenitor cells.

6.1. Biliary Intraepithelial Neoplasia

Biliary intraepithelial neoplasia (BilIN) is the main common precursor of CCA [165]. BilIN can appear as a non-invasive, microscopic, flat, micropapillary (a papillary projection with a fibrovascular stalk) or pseudopapillary (a papillary projection without a fibrovascular stalk) lesion with dysplasia. Macroscopically, although these entities may present with fine granularity, thickened velvety mucosa, or effacement of underlying tissue layers, in several cases, they can appear as grossly normal [166–168]. In addition, multicentricity is common. In 2019, the WHO classified BilIN into two histological entities, namely, those of high and low grade, with high grade categorized as a carcinoma in situ [167]. BilIN is found in hepatolithiasis, PSC and choledochal cysts, and in cirrhotic livers from non-

biliary diseases [168]. Usually, BillIN is asymptomatic and not detectable by diagnostic studies [166].

6.2. Intraductal Papillary Neoplasia of the Bile Duct

Intraductal papillary neoplasia of the bile duct (IPNB) is a macroscopic premalignant lesion (Figure 6) that may arise within intra- or extrahepatic bile ducts [169–174]. Macroscopically, IPNBs present as detectable papillary, polypoid, greyish brown or white, soft tissue growths inside an enlarged bile duct, in which it is possible to find mucus. Like pancreatic intraductal papillary mucinous neoplasm (IPMN), IPNB is histologically classified into four types: intestinal, pancreatic biliary, gastric, and oncocytic subtypes [170–174]. Intestinal and pancreatic biliary are the most common subtypes, and high-grade dysplasia is usually massive, thus signalling the presence of invasive cancer (Figures 7 and 8) in approximately half of cases. Therefore, surgical resection is suggested for this entity [170].

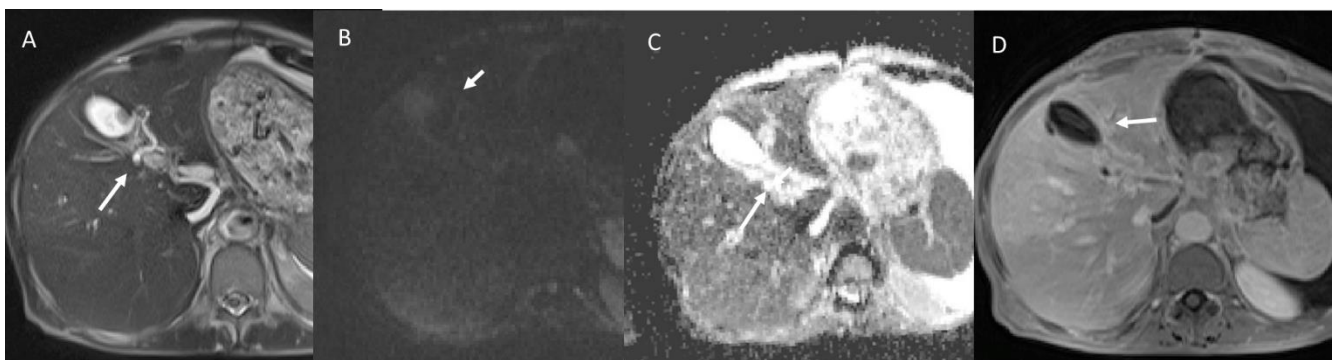


Figure 6. MRI of a 48-year-old female patient with intraductal papillary neoplasms of the bile duct, which were shown to be enlarged in the bile duct (in (A): T2-W sequences, white arrow), in which is possible to find mucus. In Diffusion-weighted-imaging assessment ((B): b800 s/mm²; (C): Apparent Diffusion Map), the lesion (white arrows) shows no restricted diffusion due to mucus. In post-contrast evaluation (in (D): Volumetric interpolated breath-holding examination T1-weighted sequence in portal phase), there is no contrast enhancement (white arrow).

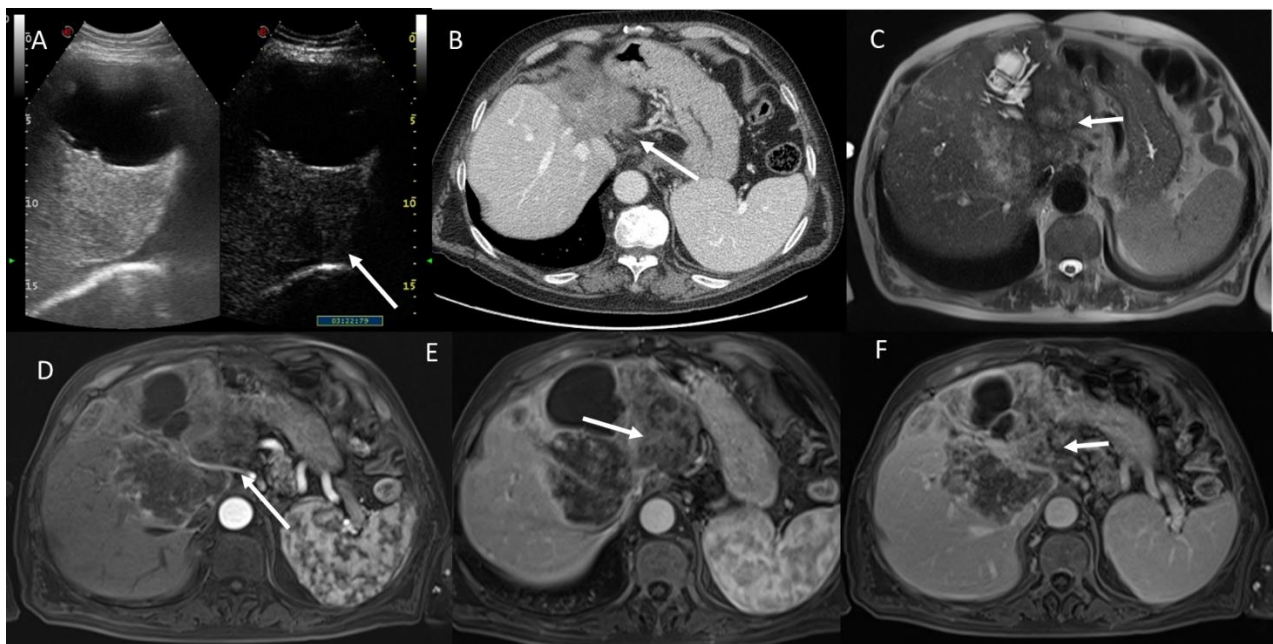


Figure 7. Imaging assessment of degenerated intraductal papillary neoplasms of the bile duct in a 78-year-old patient. (A) Contrast-enhanced ultrasound evaluation, with progressive contrast enhancement of invasive lesion component (white arrow). This pattern (white arrow) is also present

in CT assessment ((B): portal phase) and in MRI contrast study (Volumetric interpolated breath-holding examination sequence in (D): arterial phase, (E): late arterial phase, and (F): portal phase). In T2-weighted sequences (C), the invasive component shows inhomogeneous iso-hyperintense signal (white arrow).

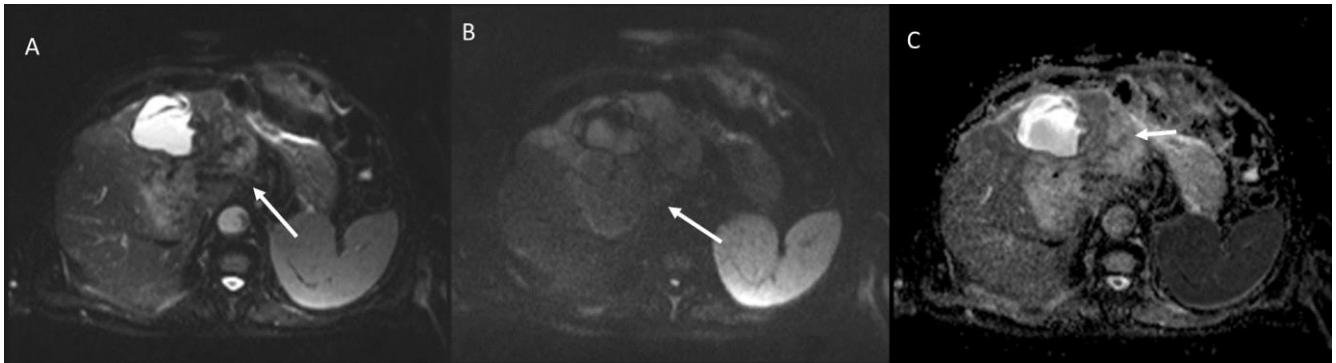


Figure 8. The same patient of Figure 7. Diffusion weighted imaging assessment ((A): b50 s/mm²; (B): b800 s/mm²; (C): Apparent Diffusion Coefficient map) the lesion shows restricted diffusion (white arrows in (A,B)) and targetoid appearance in apparent diffusion coefficient map (white arrow in (C)).

IPNB is correlated with PSC, congenital biliary tract disease, hepatolithiasis, and liver fluke infections. These tumors, single or multiple, can cause large duct obstruction with abdominal pain, cholangitis, and cholestatic hepatic dysfunction [171].

6.3. Intraductal Tubulopapillary Neoplasms of the Bile Duct

Intraductal tubule-papillary neoplasms of the bile duct (ITPNs) constitute a new entity characterized by a tubular growth pattern in the large intrahepatic and extrahepatic bile ducts that is associated with invasive cancer at the diagnosis [171]. ITPNs appear as a polypoid or solid tumor inside a dilated bile duct [172]. Compared to IPNB, ITPNs have a better prognosis [173,174].

6.4. Hepatobiliary Mucinous Cystic Neoplasm

Hepatobiliary mucinous cystic neoplasms (HMCNs), previously defined as cystadenoma (Figure 9) or cystadenocarcinoma (Figure 10), include neoplastic mucinous and/or non-mucinous biliary epithelia surrounded by ovarian-type mesenchymal stroma [175]. This entity is rare, representing less than 5% of all hepatic cystic neoplasms that are detected in women during the fourth or fifth decade of life [176–178].

HMCNs have either low-grade dysplasia or malignant features with high-grade dysplasia [179].

6.5. Diagnostic Management

For the detection of lesions with MRI combined with a functional assessment, including a DWI, the combined use of a hepatospecific contrast agent and cholangiography sequences constitute an optimal modality since it allows for the assessment of the lesion and its relationship with the biliary branches and the contiguous hepatic parenchyma [180,181], thereby permitting proper treatment planning.

Since almost all of these precursor lesions are found in patients at risk for iCCA, such as those with PSC, congenital biliary tract disease, hepatolithiasis, and liver fluke infections, and as surveillance protocols with periodic (6–12 months) imaging of the liver by US, MRI/MRCP, or CT combined with serum CA19-9 measurement have been proposed for several groups [9,10], it is clear that for all newly detected lesions inside a biliary duct, a proper multidisciplinary evaluation should be proposed. Although these precursor lesions

are rare entities, the possibility of characterizing them in the early stage facilitates the improvement of patient survival and reduces costs due to invasive procedures that could affect patients' quality of life. In addition, it is evident that these conditions should be managed in dedicated and expert groups including surgeons, radiologists, pathologists, and molecular biologists to avoid unnecessary treatment and to achieve improved patient management [180]. With regard to imaging tools, although CT and US are the main modalities and are often the first tools employed, for a correct characterization and evaluation of bile ducts, MRI should be performed for all doubtful cases. To the best of our knowledge, no standardized protocols have been suggested; however, it is critical that these patients are assessed in cancer centers [180].

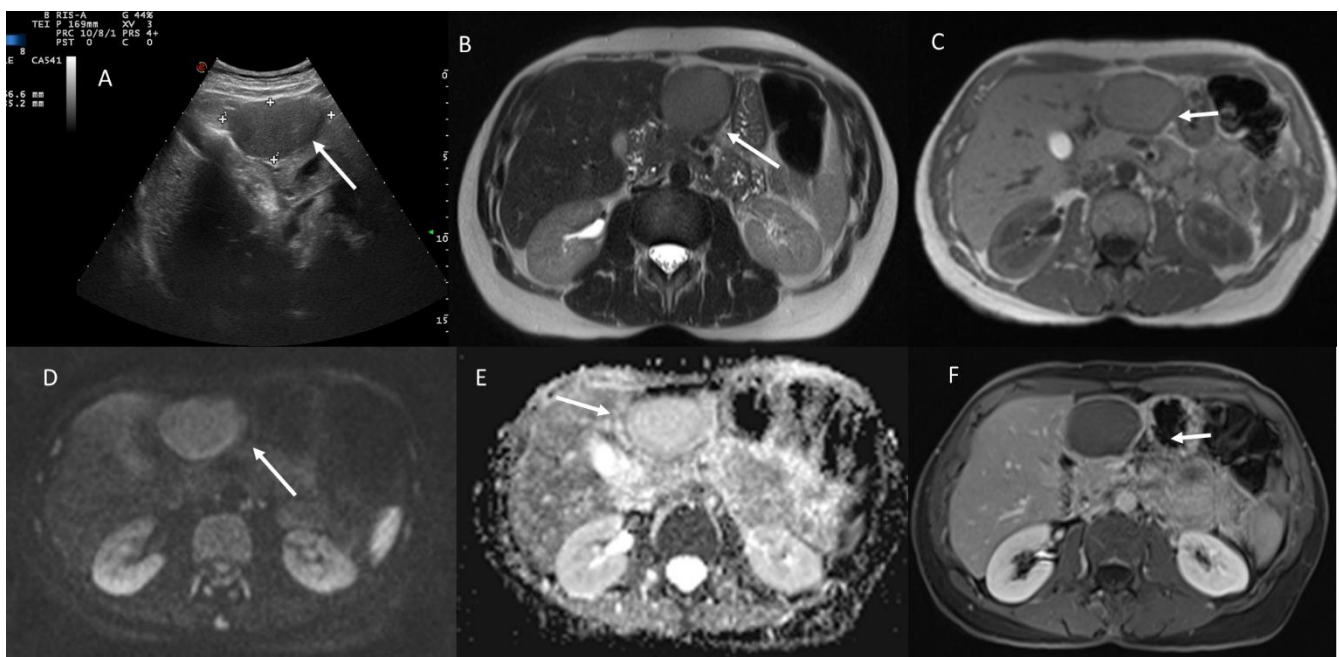


Figure 9. US (A) and MRI (B–F) assessment of cystadenoma patient. Upon US (A), the lesion shows solid appearance (white arrow), while in T2-weighted sequences (B) and T1-weighted imaging (C): in phase it shows non-solid pattern (white arrows) with restricted diffusion (D): $b800 \text{ s/mm}^2$ and (E): Apparent Diffusion Coefficient map) and peripheral contrast enhancement (white arrow) in T1-weighted sequence in portal phase of contrast study.

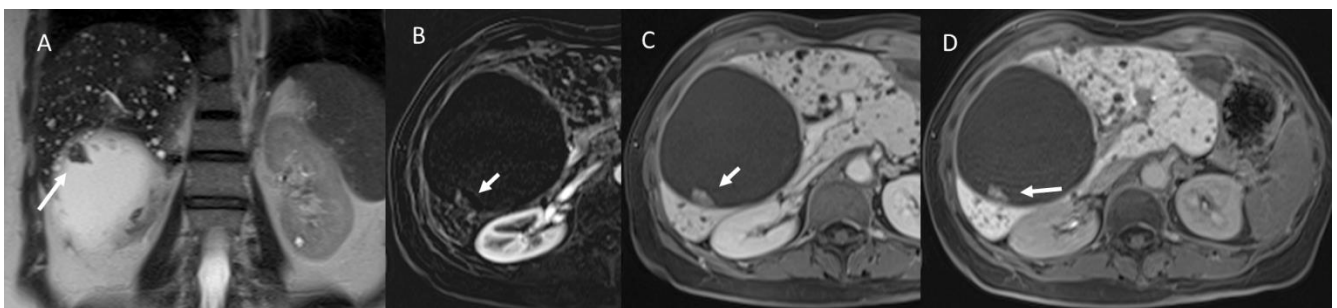


Figure 10. MRI assessment of female cystadenocarcinoma patient. The white arrows show papillary soft tissue growths inside cystic lesion with solid appearance in T2-weighted (A) and progressive contrast enhancement during arterial (B) (subtract phase), portal (C), and liver-specific phase (D) using T1-weighted post contrast sequences (volumetric interpolated breath-holding examination sequence).

7. Artificial Intelligence, Radiomics, and Cholangiocarcinoma

The latest scientific developments have improved the use of artificial intelligence (AI) in the medical setting. Since computers can accumulate and assess higher volumes of data compared to the human brain, AI can resolve difficulties in the oncological setting [182–198]. AI is a branch of computer science that develops algorithms trained to execute functions that are normally performed by the human brain [198–210]. Machine learning (ML), a sub-area of AI, is based on computer models that can learn specific tasks through the replication of computations resulting from considerable volumes of data [211–228]. These models evaluate data using mathematical algorithms that are frequently corrected until the analysis yields the required outcome. These models can be supervised or unsupervised, and their applicational diversity corresponds to the computerized knowledge of the desired outcome of interest [229–238]. In the supervised form, a training dataset (the “input”) is introduced to obtain the desired outcome (the “output”). Therefore, the ML model analyzes the input, producing the necessary adjustments to obtain the desired output [239–251]. This type of learning requires great volumes of training data that have been “curated”, that is, pre-labeled by a human operator. Once the training is completed, a different dataset (testing data) is used to test the model’s performance [252–260]. In unsupervised learning, the model assesses un-curated data, classifying the data due to defined features within the dataset that can be grouped and analyzed further to reach a specific outcome [261–280].

To date, many of the ML models utilized in the clinical setting have been supervised, and these models have enabled the development of a new approach named Radiomics [281–291]. Radiomics is based on the extraction by digital images of data that can be analyzed in a mathematical way [281–291]. The idea that imaging studies contain a great quantity of data, in the form of grey-level patterns, which are imperceptible to the human eye, has become increasingly interesting [292–294]. These texture features, when correlated with clinical-pathological data and outcomes, theoretically allow for diagnostic and prognostic assessment [295–298] (Figure 11 reports a typical flowchart of an artificial intelligence model).

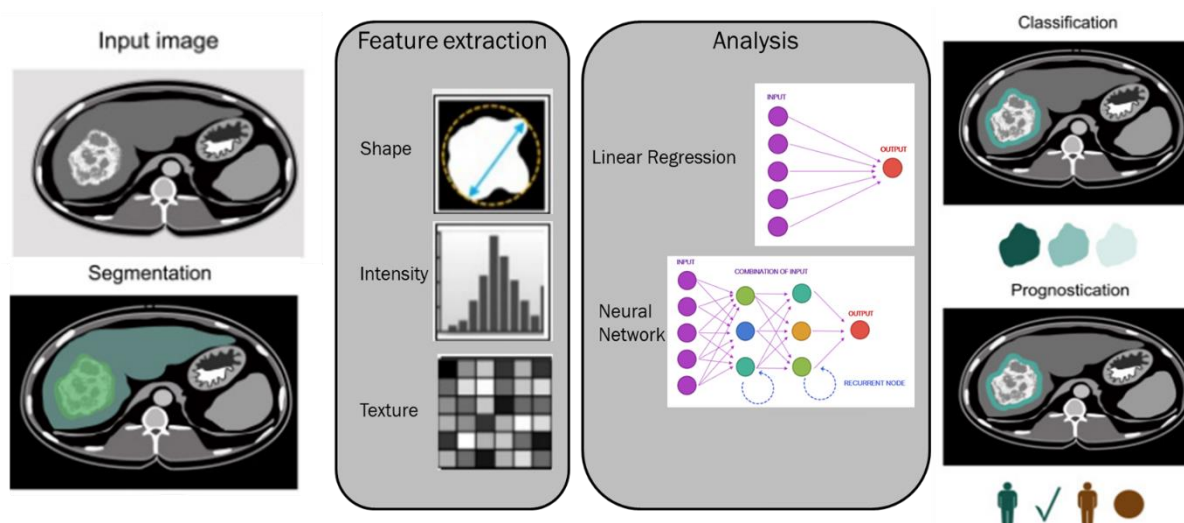


Figure 11. Flowchart of artificial intelligence model.

The assessment of textural characteristics, obtained by conventional radiological images, such as CT or MRI, allow for the extraction of biological data using a non-invasive approach, thereby reducing costs and time and avoiding any risk for the patients. For several tumors, radiomics analyses have already provided accurate evaluations of their biology, thus allowing for the identification of features correlated with clinical outcomes [299–306].

The merit of this new tool is that it is able to obtain digital data from medical imaging and, when performed under appropriate protocols, is more robust and reproducible.

Nevertheless, there are remaining issues in the clinical setting. First, reproducibility is a very important issue. This is correlated with several features, such as the acquisition protocol, the method of segmentation, the method for extracting the imaging features, and the acquisition of clinical and genomic data.

In the context of iCCA, the possibility to identify a lesion at an early stage or in a pre-malignant setting may allow for its proper management [307]. Therefore, several researchers have evaluated AI in the CCA setting.

Only few authors have evaluated the possibility of assessing iCCA at an early phase. Xu et al. [308] established a support vector machine (SVM) based on radiomics features obtained by non-enhanced CT to train a discriminative model to recognize HCC and ICCA at an early stage. They showed that compared to radiologists, their model offered significantly better performance with respect to distinguishing HCC from ICCA. Ichikawa et al. [309] obtained similar results.

Logeswaran et al. [310] proposed a CAD system, the multi-layer perceptron (MLP), to automatically detect CCA using a single MRCP image. MLP, a form of ANN, was employed to distinguish patients with and without CCA. Comparing this AI system to previously available systems, MLP was found to be better in terms of the detection of CCA (88.03% vs. 86.17%), healthy tissue (83.64% vs. 76.90%), and non-cholangiocarcinoma lesions (90.14% vs. 80.99%) [310].

Future studies on the possibility of identifying the precursors of CCA, incorporating the ability to evaluate liver parenchyma in which a lesion is not yet visible to the human eye, are desirable. This would allow for the definition of diagnostic-therapeutic programs centered on a single patient.

8. Discussion

The primary end point of cancer screening is to reduce tumor-related mortality by detecting cancer at an early stage and preventing its occurrence by identifying and treating pre-malignant lesions in asymptomatic patients [200]. However, at the time of diagnosis, iCCA is often metastatic or in a locally advanced stage. So, the identification of higher-risk patients, defined by genetic and predisposing diseases, using appropriate diagnostic tools is desirable [200].

However, the potential hazards of screening programs comprise adverse events associated with diagnostic procedures and patient anxiety [132]. In addition, potential over-diagnosis or misdiagnosis may occur, causing an over-treatment of completely benign or low-risk neoplastic lesions [132].

Today, in the iCCA context, proper surveillance protocols are only proposed for a few categories, such as PSC or cirrhosis patients, although, in this case the pre-existing programs are designed for HCC risk. So, due to the incidence and high mortality rate of iCCA, which are also correlated with a late diagnosis, dedicated programs of screening should be considered. In addition, knowledge of the precursor lesions is critical to avoid a misdiagnosis. In fact, the major limitation is the incapacity to detect and characterize premalignant lesions. The possibility to utilize AI models to evaluate higher-risk patients could benefit the diagnosis of these entities, although more data are needed to support the practical utility of these applications in the field of screening.

At present, with regard to iCCA, the main clinical setting in which radiomics is employed is treatment, either proper treatment selection such as ablation therapy [311] or for early recurrence, e.g., after surgical resection [312–316]. However, these applications correspond to a late disease status, whereas the ability to identify precursor lesions as soon as possible should improve overall survival. AI allows for the performance of the image-based, extensive analysis of such minute alterations and the identification of potential risk predictors for disease. AI systems, as opposed to manual approaches, execute complex tasks without interruption and ensure highly accurate and precise outcomes. In the domain of the automated processing and analysis of medical images, AI offers numerous techniques and tools with which to extract accurate measurements from different structures, and

can identify nonlinear features and evaluate tissue properties. For prediction modelling, radiomics analysis as well as machine and deep learning are regarded as the most reliable and common AI approaches. The main issues remain those related to the dataset employed, which should include a large number of data, so that, in rare conditions, even few results can be robust and reproducible.

Accordingly, it would be appropriate to realize screening programs in the research protocols setting. In fact, the success of these programs requires patient compliance and multidisciplinary cooperation [132].

9. Conclusions

Although the knowledge on iCCA is increasing, currently, its diagnosis in a late stage is correlated with a high rate of patients that are unfit for surgical treatment. Dedicated surveillance programs have been proposed for patients in a few at-risk categories. Improved stratification of patients according to the underlying liver disease and the introduction of AI systems and Radiomics models may lead to better patient management, which should include a multidisciplinary team of experts and a dedicated study protocol to optimize time, personnel, and economic resources.

Author Contributions: V.G. wrote the initial manuscript. All authors contributed equally to this manuscript. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Data Availability Statement: All data are available in the manuscript and at link <https://zenodo.org/record/7576415#.Y9PrT3bMK3A> (accessed on 1 November 2022).

Acknowledgments: The authors are grateful to Alessandra Trocino, librarian at the National Cancer Institute of Naples, Italy.

Conflicts of Interest: The authors declare that there are no conflict of interest.

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