

Digital pathology, image analysis, and artificial intelligence in liver disease

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Advances in digital pathology, image analysis, and artificial intelligence (AI) are rapidly transforming how pathologists and researchers interact with tissue samples and enable the development of diagnostic tools that harness high-resolution whole-slide images; these advances are in turn creating new opportunities for research, education, and routine clinical care globally. Liver disease is no exception, and digital pathology and AI have many applications in the diagnosis of liver cancer and liver diseases and in the assessment and management of transplantation. Although quantitative image analysis techniques have been applied to liver disease in research settings for over 50 years, recent improvements in image resolution, data storage, and the availability of advanced AI methods such as deep learning have driven multiple exciting developments. In this Review, we summarise the advancements in digital pathology, image analysis, and AI in liver disease. Key challenges such as access to and the logistics of using digital solutions, quality issues, and appropriate guidance in research and clinical use are reviewed, along with potential solutions to these challenges in the context of liver pathology and liver disease. Digital technologies are well established in liver pathology research, and access in clinical practice is increasing, with potential to address current laboratory challenges. Further evaluation is required to assess real-world effectiveness, clinical safety, and implementation of AI tools in liver pathology.

Introduction

Liver disease causes approximately two million deaths per year and results in substantial global morbidity.¹ Liver pathologists play an important role in diagnosing liver disease; providing information on disease severity, prognostic features, suitability for specific therapies, and eligibility for clinical trials; and assessing donor organs for transplantation.² The demand for liver pathology services is high, and many tasks performed by the pathologist are labour-intensive, quantitative, and time-pressured—tasks that might be assisted by digital solutions.^{3,4}

Digital innovations continue to emerge across medical settings and specialties, with potential benefits for both patients and health-care professionals.⁵ Workforce challenges, waiting times, and insufficient resources have increased the demand for digital solutions in clinical practice.⁶ For example, within histopathology, 97% of UK laboratories reportedly do not have adequate staffing to meet demand, and similar concerns exist in other regions as well.^{7–10}

The role of artificial intelligence (AI) in hepatology has recently been reviewed.^{4,11,12} Liver pathology is an ideal domain for the use of digital imaging. First, its specialised nature, with few practitioners and expertise often centralised in referral and transplant centres, supports the need for efficient diagnostic workflows through digital pathology.¹³ Second, liver pathology is a key area in which image analysis for disease quantification has been used successfully for some time in research settings (eg, in fat or collagen proportionate area [CPA] quantification) and hence is likely to adopt computational pathology rapidly.^{14–16}

In this Review, we comprehensively discuss developments in digital pathology and computational image analysis for liver disease, including both inflammatory and neoplastic conditions. The Review is organised by liver disease areas as established in the literature, while

accepting that clinical service organisations vary across laboratories and regions. Note that this Review is not intended to be an exhaustive description of all advancements but provides an overview of key progress in the field of digital pathology in liver disease. Furthermore, this work also highlights the challenges in digital liver pathology. The terms used in this Review are defined in the panel.

Digital pathology

Research and clinical practice

Since 2015, digital pathology has evolved from being primarily a research tool to becoming a routine part of clinical practice.²⁵ High-resolution digital images of tissue are increasingly and conveniently available to pathologists, with no requirement for paper request forms or physical collection of glass slides.^{26,27} Whole-slide images generated by scanning entire glass microscope slides, together with storage solutions for large volumes of image data, enable deployment of the technology at scale for routine clinical use (figure 1).^{26–29}

Digital images of microscope slides have been available as telepathology images or digital photographs for decades. Telepathology, the transmission of live microscopic images, is generally considered a precursor to contemporary whole-slide imaging and was introduced in the 1960s.³¹ Early whole-slide imaging systems were described in the 1990s but faced substantial challenges in scanning speed and image storage.¹⁷ Existing systems can scan dozens of slides per hour, with physical and cloud-based solutions for huge image data storage capacity, making full digitisation of research or clinical laboratories a distinct reality.^{28,32,33}

Digital pathology use in clinical practice is increasing, with applications in primary diagnosis, remote working, second opinions, and rapid transplant sample evaluation.^{3,29,34,35} Digital pathology improves access to rapid specialist review of liver biopsies and facilitates sharing and

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Panel: Terms used in the Review

Artificial intelligence (AI): the science and engineering of developing intelligent machines or computer programs.¹⁷

Hepatocyte ballooning: a form of hepatocyte degeneration that is associated with cellular swelling, rounding, enlargement, and characteristic reticulated cytoplasm.¹⁸

Bridging fibrosis: a pattern of liver fibrosis in which fibrotic bridging extends across lobules to track between portal regions and central veins.¹⁹

Collagen proportionate area (CPA): a ratio of liver fibrosis that is estimated by measuring the areas of collagen and of liver tissue in an image, using digital image analysis techniques.¹⁵

Concept attribution: an explainability approach in which the estimated relevance of defined features within an image to an AI model's prediction is shown to the user in the form of relevance scores.²⁰

Digital pathology: a generic term for digital imaging in pathology, but usually refers to images created by whole-slide imaging technology.²¹

Digital pathology validation: a pathologist-led, self-validation continuous learning process that includes training in using the digital pathology system and comparison of diagnoses on glass and digital slides using a test set and live cases.²¹

Image analysis: a general term that refers to techniques that allow interpretation or gathering of information or parameters from an image.²²

Non-alcoholic steatohepatitis activity score (NAS): a semiquantitative scoring system designed to assess the range of histological appearances seen in non-alcoholic fatty liver disease or metabolic dysfunction-associated steatotic liver disease, including steatosis, lobular inflammation, hepatocellular ballooning, and fibrosis.²³

Reporting guidelines: guidelines for reporting of research that set the minimum essential information required to improve the accuracy and transparency of publications.²⁴

Saliency maps: an explainability approach in which the estimated relevance of each group of pixels in an image, in relation to an AI model's prediction, is highlighted using a visual heatmap overlay.²⁰

Trust scores: an explainability approach in which estimates of the uncertainty of an AI model are provided to the user to assist with understanding the limitations of the model. These measures can be viewed as overlays on the image or as confidence intervals on the model output.²⁰

Whole-slide imaging: a scanning technology that allows the digitisation of an entire glass slide to create a digital image for review.²¹

discussion of complex cases. Additional expert review is crucial to increase concordance and diagnostic quality in pathology.^{36–38}

Digital pathology in liver disease has been explored specifically in CPA, steatosis, and fibrosis image analyses for some years.^{39–41} Digital imaging offers advantages in liver pathology, for example, when used in repetitive quantitative tasks and in transplant settings, in which specimen diagnosis is urgent, and requires a pathologist to be physically present, frequently after routine working hours.

Digital pathology is used often in tissue-based research and clinical trials. The technology enables rapid case accrual, central pathology review, easy access to international pathologist expertise, and secondary image analysis, such as haematoxylin and eosin (H&E) staining or immunohistochemistry-based analysis.⁴² Digitisation of clinical trials offers further advantages. Intraobserver and interobserver variations are well recognised when using semiquantitative scoring systems and diagnostic or grading tasks in pathology.^{43–45} As such, quantitative image analysis techniques are increasingly useful in clinical trials, during which consistency across cohorts is important.

Guidance and validation

Increased access to digital pathology requires consideration of the general changes to routine practice (both in the short and long term) such as changes to laboratory workflows,

access to AI and other tools, changes in staff training needs, associated flexible and remote working and access to appropriate hardware and software, and measures to minimise safety risks of these tools. Professional bodies, including the Royal College of Pathologists (RCPATH) and the College of American Pathologists (CAP), have developed guidance on implementing and using digital pathology in clinical practice.^{21,46} A key element of this guidance is digital pathology validation to ensure that the accuracy of digital diagnosis is not inferior to that of diagnosis using a microscope. Both RCPATH and CAP recommend a validation process before pathologists move from light microscopy to digital pathology in routine clinical practice.^{21,47–49} Pathologists usually undertake several stages of validation, including a period of using both light microscopy and digital pathology, to allow for adjustment. Validation also provides an opportunity for learning and feedback when re-reviewing diagnoses, especially in case of any discordance between digital microscopy and the reference standard of light microscopy. Guidance is also available for the technical implementation of digital pathology systems at scale and for the practical considerations for routine use.^{21,26,46}

Steatotic liver disease

Alcohol-related liver disease and metabolic dysfunction-associated steatotic liver disease (MASLD; formerly known as non-alcoholic fatty liver disease) represent a substantial

global health burden, with increased disease-related mortality expected in the coming decades.^{50,51} In the Americas, alcohol-related liver disease and MASLD are replacing viral hepatitis as the leading cause of cirrhosis.⁵²

Fatty liver disease poses a particular challenge to histopathologists because of high biopsy volumes, evolving nomenclature, and interobserver variation. The issue of interobserver variation in relation to hepatocyte ballooning is particularly problematic, both because this histological feature shows large variability between observers, and because it is a key determinant of fatty liver disease severity assessment. MASLD is the most common indication for clinical liver biopsy and is the focus of many clinical trials, most of which use histology as the primary endpoint. Additionally, the most widely used scoring system—namely, the non-alcoholic steatohepatitis activity score (NAS)—has some limitations with the variation in pathologists' interpretations and has been subject to recent critiques⁵³ and modifications.⁵⁴ NAS shows considerable interobserver and intraobserver variation, with interobserver agreement ranging from κ 0.20 to 0.77 (fair to substantial) among four pathologists for overall diagnosis in one study.⁵⁵ Taken together, all these factors have encouraged the application of computational pathology to fatty liver disease.

Image analysis in steatotic liver disease

Fatty liver disease was an early domain to benefit from image analysis in research settings. Before the development of modern deep-learning methods, analysis was limited to tasks with strong colour contrast between background features and the pathological entities being measured. These approaches focused on fibrosis and fat.

Fibrosis

Interest in the assessment of fibrosis was initially focused on liver biopsies with hepatitis C virus. However, because liver biopsy is no longer required in standard cases of hepatitis C virus or clinical trials, this application is now largely of historical relevance. Fibrosis stage during liver biopsy indicates the progression of the liver towards cirrhosis. As with inflammatory activity, histological fibrosis is routinely assessed in both clinical practice and clinical trials using semiquantitative scoring systems, such as the modified histological activity index (Ishak) for chronic hepatitis and the non-alcoholic steatohepatitis (NASH) clinical research network (CRN) scoring system for metabolic dysfunction-associated steatohepatitis (MASH).^{56,57}

The first method used to assess fibrosis was conventional image analysis of Sirius Red-stained sections.⁵⁸ The percentage of the section composed of collagen is termed the CPA. CPA provides a reproducible measure of fibrosis with less interobserver variation than that observed using conventional semiquantitative scoring systems and can be obtained using freely available software (eg, QuPath⁵⁹ and ImageJ⁶⁰). CPA correlates with histological scores; however, there is much overlap between CPA values and histological scores in both chronic hepatitis (especially hepatitis C virus)

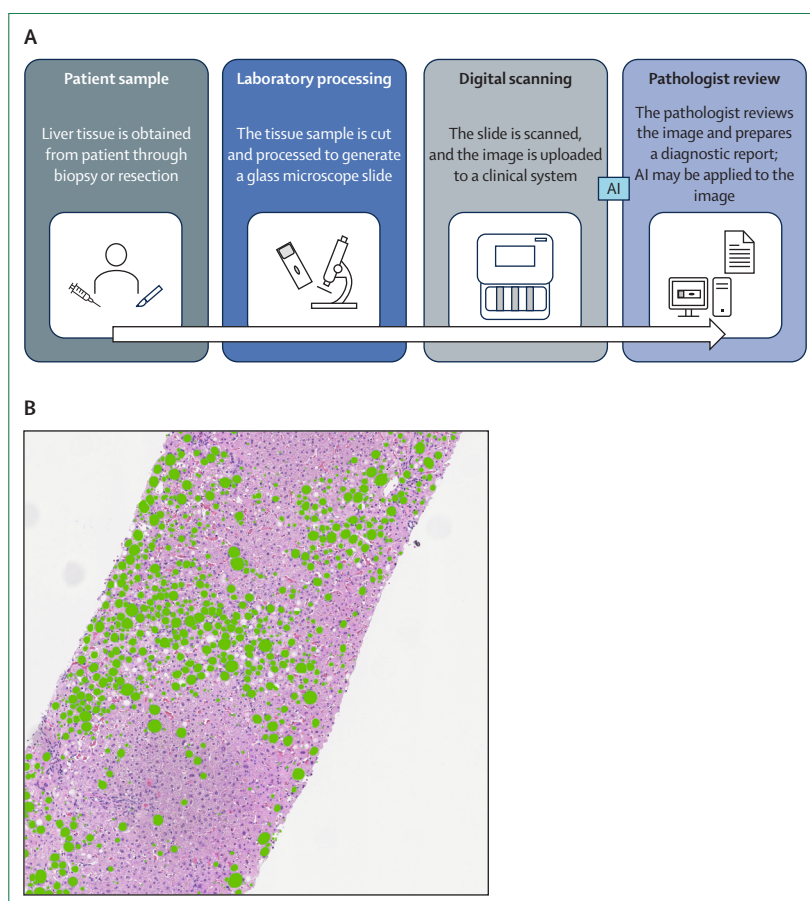


Figure 1: Summary of a digital pathology workflow

A sample of liver tissue is sent to the histopathology laboratory for macroscopic examination, sectioning, and processing. A glass slide is produced at the end of this process. This slide is scanned to generate a high-resolution digital image on a clinical system for review by a pathologist. Once the slide is scanned, image analysis or AI can be applied to digital pathology images. The pathologist prepares a diagnostic report using digital images instead of a microscope. (A) Summary of workflow to produce a pathology report using digital pathology in routine clinical practice. (B) Example mark-up image of an area of liver biopsy core for digital pathology assessment. Image analysis software LiverQuant³⁰ has been applied, and green circles delineate areas of steatosis detection within the tissue. AI=artificial intelligence.

and MASH.⁵⁸ This approach has also been applied to smooth muscle actin-stained sections to assess stellate cell activation.⁶¹

CPA predicts outcomes in several clinical settings, including alcoholic⁶² and non-alcoholic liver disease.⁶³ Several studies have shown that the subclassification of cirrhosis based on the thickness of fibrous septa has prognostic value.⁶⁴ CPA is also a reliable technique for this subclassification of cirrhosis. In one study, CPA was the only independent predictor of clinical decompensation in a cohort of patients with cirrhosis.⁶⁵

The most important disadvantage of CPA is that because it is a simple area-based measure of collagen staining, it does not capture or describe architectural changes. CPA is also subject to artifacts such as the fibrosis seen in subcapsular areas in liver biopsies and fibrosis associated with blood vessels. Often, there are only slender septa of collagen

around the nodules in biopsies from cirrhotic livers, leading to an underestimation of the amount of fibrosis in the liver. There is scarce evidence for the reproducibility of CPA across laboratories, with one study reporting greater variation than anticipated.⁶⁶ This variation was largely because of differences in interlaboratory and intralaboratory staining. Although widely used in research, CPA is not used in clinical practice or major clinical trials.

Fat

Interest in image analysis of fat has increased in parallel with the developing interest in steatotic liver disease, and fat is relatively straightforward to analyse.⁴⁰ Image analysis provides quantitative rather than semiquantitative information. An early finding was that histopathologists gauging steatosis extent by eye tend to overestimate the amount of fat in histological sections when compared to quantitative image analysis.⁶⁷

AI in steatotic liver disease

Modern machine learning-based image analysis enables the analysis of H&E-stained images (general applications are summarised in figure 2). This topic has been recently reviewed by Ratzliff and colleagues.⁶⁸ An early study in this field was that by Forlano and colleagues.⁶⁹ They described an automated image analysis system to assess steatotic liver disease, using a development cohort of 100 patients and a validation cohort of 146. In the development cohort, the interclass correlation coefficients between pathologist assessments and machine assessments were 0.97 for steatosis, 0.96 for lobular inflammation, 0.94 for ballooning, and 0.92 for fibrosis. In a subgroup of paired liver biopsies, quantitative analysis was more sensitive in detecting differences than manual semiquantitative scoring by a pathologist. Studies have highlighted the advantages of this approach in clinical trials, including generation of reproducible, continuous measures of liver injury.^{70,71}

In a subsequent study, Taylor-Weiner and colleagues⁷² described a machine learning-based approach, which they applied to data from three randomised controlled trials (involving 3320 patients in total). They developed and validated a deep convolutional neural network, which identified and quantified NAS components and fibrosis. This approach correlated not only with the assessments of specialist liver histopathologists but, importantly, also with the progression of fibrosis and clinical outcomes. The levels of agreement between pathologists and the model were within the range observed among expert pathologists. The Deep Learning Treatment Assessment (DELTA) Liver Fibrosis score, which measures antifibrotic treatment effects not identified by routine histological assessment, correlated with clinical progression. The main reason for this correlation was that this approach accounted for heterogeneity of the changes in fibrosis in any given biopsy. Such heterogeneity is not assessable by pathologists and is a major source of error. A 2025 study reported the clinical validation of an AI

tool to score features of MASH and showed noninferiority of the model when compared with manual scoring.⁷³

New tissue imaging techniques applied to the liver

New tissue imaging techniques have been developed alongside advances in analytical methods. These techniques include non-linear optical microscopy techniques such as the second harmonic-generation (SHG) and two-photon excited fluorescence (TPEF) microscopy.^{74,75} TPEF microscopy shows the overall structure of the liver, whereas SHG microscopy enables the identification and analysis of collagen. The simultaneous use of these two techniques allows for the automatic precise localisation of fibrillar collagen and its detailed characterisation in both two and three dimensions, as shown by Soon and colleagues.⁷⁶ The authors concluded that the SHG-derived algorithms can detect subtle changes in liver fibrosis, using a continuous scale. SHG microscopy could be used to improve fibrosis endpoints in MASH trials, in which a decrease of at least one point in fibrosis staging is unrealistic given the relatively short duration of the trials.

It is important to note that new imaging technologies (and the application of AI to them) can operate independently of direct pathologist input. In contrast, the other AI approaches discussed in this Review typically require input from pathologists during development or evaluation. However, this independence currently applies only to fibrosis. When the same or other AI methods are applied to additional histological features of MASH, such as inflammation or hepatocellular ballooning, the complexity increases. A 2022 study showed poor agreement among expert liver pathologists in identifying ballooned hepatocytes, which represent a key histological feature of steatohepatitis.⁷⁷ The advantages of SHG microscopy in fibrosis were shown in a study of hepatitis B virus.⁷⁸ The authors developed a quantitative measure of fibrosis (qFibrosis) based on 87 parameters. qFibrosis could considerably predict the underestimation of fibrosis stage in inadequate biopsies (<15 mm in length) compared with subjective scoring by pathologists. These additional physical features might offer substantial advantages for qFibrosis across all aetiologies of liver disease.

qFibrosis has also been applied to biopsies from patients with MASLD using the quantifiable fibrosis-related parameter (q-FP).⁷⁹ The authors used dual-photon microscopy-based quantitation of fibrosis, which could clearly identify both collagen deposition sites (general, vessel, perisinusoidal, and vascular septa) and their characteristics. For data from 70 patients, q-FPs showed interobserver and intraobserver agreements of at least 0.8 and correlated with pathologist assessment of fibrosis. Sixteen of the most reproducible parameters were included in principal component analysis. Thus, the approach could reliably distinguish no fibrosis from fibrosis (area under the curve=0.88) and cirrhosis from non-cirrhosis (area under the curve=0.93). The study also showed that four q-FPs—namely, collagen strand number, strand length, strand eccentricity, and strand

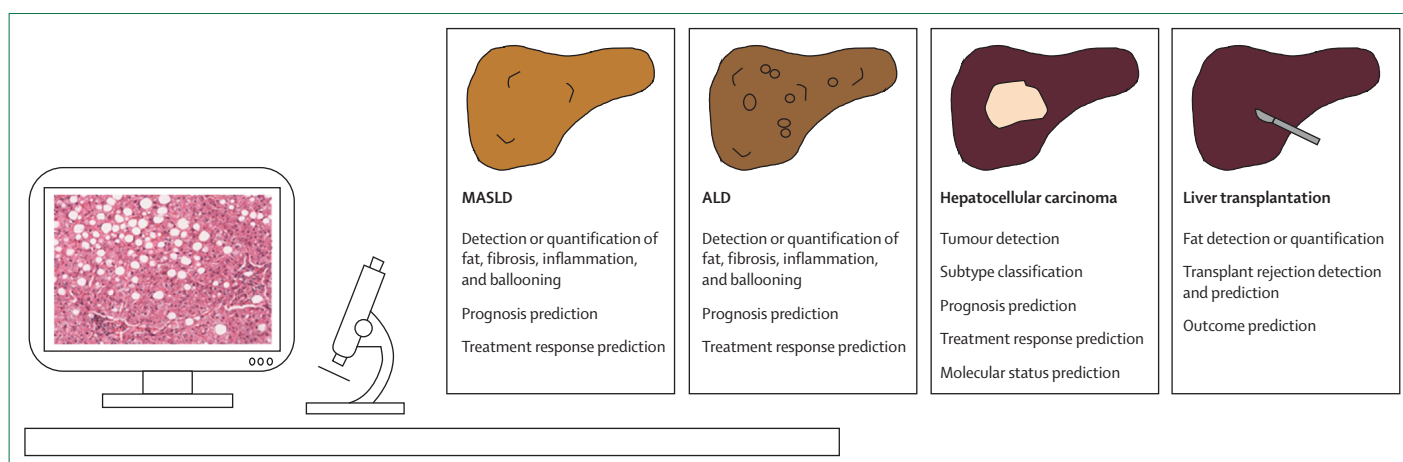


Figure 2: Applications of image analysis and AI technologies in digital pathology for liver disease

Detection, classification, and prediction tasks might be performed in MASLD, ALD, hepatocellular carcinoma, and liver transplantation. AI=artificial intelligence. ALD=alcohol-related liver disease. MASLD=metabolic dysfunction-associated steatotic liver disease.

solidity—were independently associated with fibrotic stage; the q-FPs were used to model fibrosis along a continuous linear scale using a desirability function. This measure also correlated with NASH CRN fibrosis stage.

Building on previous work using SHG and unstained sections, Chang and colleagues⁸⁰ developed a new measure of fibrosis in patients with MASLD, termed the SHG B-index, which was developed using AI. The B-index, a continuous variable derived from 14 collagen properties, showed good correlation with histological stage. An index greater than 1.76 had an overall diagnostic accuracy of 99% for predicting bridging fibrosis (Brunt stage ≥ 3), with sensitivity of 88%. This finding is important as the development of bridging fibrosis is a crucial step in the development of intrahepatic shunting and, thus, an important milestone in the evolution of liver disease.

qFibrosis (as described above) was modified by Liu and colleagues⁸¹ in a study of MASLD in adults and children. This study is important because MASLD in children has been highly under-represented in existing studies, and differences exist in the patterns of disease, with the fibrosis being portal based in children and perivenular in adults. The authors concluded that SHG analysis correlates with NASH CRN staging and reveals differences and similarities in collagen deposition in the two age groups. They reported greater baseline collagen in adults than in children and quantified differences between portal and perivenular fibrosis in both groups. The authors extended their work by combining SHG and TPEF microscopy to develop new measures for fibrosis (known as qFIBS), inflammation (qInflammation), hepatocyte ballooning (qBallooning), and steatosis (qSteatosis).⁸² The work was carried out in both paediatric and adult patients with MASH. The authors concluded that, although their automated approach generated continuous measures for all these features, it was less effective in assessing inflammation and ballooning.

A 2022 study examined paired biopsies from 99 patients in a clinical trial of tropifexor (a non-bile acid farnesoid X receptor agonist).⁸³ The study showed that treatment with tropifexor led to an overall decrease in liver fibrosis (qFibrosis score); this decrease was, however, not identified using conventional pathological techniques. There was also a marked decrease in perisinusoidal fibrosis in patients with F2 or F3 fibrosis at baseline, with the greatest reductions in those with the largest decrease in qSteatosis. In patients with bridging fibrosis, decreased septal fibrosis was identified during image analysis but not with conventional microscopy. Therefore, this finding is another example of how combining new imaging techniques with computational pathology tools can identify changes that would otherwise go unrecognised. The clinical implications of such findings remain to be established.

The study by Leow and colleagues⁸⁴ aimed to address the relative difficulty that previous studies had in assessing fibrosis in patients with mild disease. They refined qFibrosis by adding 26 portal and periportal parameters. This approach allowed for an improved stratification of stage 1 and stage 2 fibrosis, and was especially useful in screening patients for enrolment in clinical trials and assessing their treatment response.

Digitised slides are necessary for computational pathology; however, they are increasingly used by histopathologists as well, for scoring, and, therefore, it is with these scorings that the results of computational pathology are validated. Although the differences between reporting using glass and digital slides in histopathology have been studied in general,⁸⁵ there are few studies with reference to MASH.⁸⁶

Longitudinal studies have confirmed that fibrosis is the most important predictor of long-term outcomes in MASH, both in terms of morbidity and morphology.⁸⁷ Pathological fibrosis is increasingly recognised as an endpoint in clinical trials.⁸⁸ However, we do not know whether the

subtle changes in fibrosis that are detectable with these advanced techniques are clinically meaningful.

A 2022 paper emphasising the histopathological quality control issues in clinical trials discussed the pros and cons of three different AI systems and the position of the US Food and Drug Administration (FDA) regarding the work in this domain.⁸⁹ An FDA meeting in September, 2023, dealt with the requirements and processes for the approval of biomarkers of steatohepatitis, and these processes included both routine and digital pathology.⁹⁰

Disseminating images and linked clinical data is one way in which material can be made available for other users to access and is one way in which research can be facilitated across national and international borders. For example, the SteatoSITE website, based on a multicentre retrospective cohort from the UK, includes a full range of steatotic liver disease data from almost 1000 patients and includes digital images, RNA data, and extensive clinical follow-up data.⁹¹

AI has been investigated for its utility either to replace or supplement the pathological assessment of fibrosis, with the aim of improving the levels of agreement while maintaining accuracy. A small study using this approach on 120 liver biopsy samples demonstrated that the levels of fibrosis assessment in the study showed a modest improvement (from 89% to 93%) after applying an AI image analysis module to provide quantitative fibrosis (qFibrosis) values for continuous measurement and ordinal staging.⁹² A recent study showed that this approach can also be applied to inflammation and steatohepatitis.⁹³

Machine learning in liver fibrosis

The most recent approaches to assessment of fibrosis in liver biopsies have used machine learning. Studies using this approach have focused on the assessment of the presence or absence of bridging fibrosis or nodule formation. In a study of 152 whole-slide images that investigated the identification of different patterns of fibrosis in MASH, the areas under the receiver operating characteristic curves were 79% for detection of periportal fibrosis, 83% for pericellular fibrosis, 86% for portal fibrosis, and greater than 90% for detection of normal fibrosis, bridging fibrosis, and presence of nodule or cirrhosis.⁹⁴ A similar reliability was observed in another study that distinguished early fibrosis from advanced fibrosis (bridging and cirrhosis) in 79% of cases.⁹⁵

Other inflammatory liver diseases

Although the evidence for the use of pathology-based image analysis and AI research in other inflammatory liver diseases is inadequate, a few interesting examples can be reviewed. Campos and colleagues⁹⁶ developed an image analysis technique for fibrosis quantitation in hepatitis C. The quantitation correlated with staging using the Ishak and METAVIR scoring systems in trichrome-stained sections of liver biopsies. Published work that uses AI to analyse drug-induced liver injury in human tissue remains

scarce.⁹⁷ The potential of AI applications in autoimmune liver disease was reviewed by Gerussi and colleagues, who demonstrated that AI could improve clinical outcomes by improving patient stratification.⁹⁸ In 2024, a small study of 123 liver biopsies showed diagnostic accuracies of individual histological features, with a 72·4% accuracy in classifying immune cells on H&E-stained whole-slide images and an 87·6% accuracy for identifying fibrosis on Sirius Red-stained whole-slide images.⁹⁹ Finally, there is insufficient evidence for the application of image analysis techniques in haemochromatosis and Wilson's disease; however, Hall and colleagues¹⁰⁰ described semiquantitative scoring for Perls' Prussian blue staining for iron deposition using image analysis. Subsequently, Sivasubramaniam and colleagues¹⁰¹ applied an AI model for the quantitation of iron in liver samples.

Neoplastic liver disease

Research on image analysis solutions for liver cancer is increasing, with multiple developments using machine learning and deep learning. There are two main types of primary liver cancers: hepatocellular carcinoma and cholangiocarcinoma. In a prospective observational study, Kiani and colleagues¹⁰² developed neural network models to assist pathologists in accurately classifying these two tumour types. The AI model improved diagnostic accuracy among pathologists. Although less experienced pathologists gained more benefits from the model, they were also more prone to mistakes when AI predictions were incorrect. This example illustrates the broader risk of automation bias and overreliance on medical AI, especially among novice users.^{103,104} It should also be noted that the pathologists in this study only submitted small micrographs of the tumours rather than whole-slide images. Additionally, the cases included were prescreened, excluding more complex examples such as combined tumours. Well differentiated hepatocellular lesions are a major diagnostic challenge, especially in biopsies. To address this challenge, a deep-learning diagnostic model was developed, which improved the diagnostic rate of early hepatocellular carcinoma and the risk stratification of patients with well differentiated hepatocellular lesions.¹⁰⁵ The algorithm showed advantages in patch-level recognition of hepatocellular carcinoma, with important diagnostic implications for small biopsies.

A study published in 2025 reported the development of a deep-learning model to predict the development of hepatocellular carcinoma within 7 years of a steatotic biopsy in patients with steatotic liver disease.¹⁰⁶ The reported accuracies were 81·0–82·3%, with areas under the curves ranging from 0·80 to 0·84. Another study addressed the use of an unsupervised deep-learning model to identify subtypes of intrahepatic cholangiocarcinoma with different recurrence-free survival.¹⁰⁷ This model produced novel histological subtypes that enabled significant patient stratification using Cox proportional hazard models. The clinical potential of this approach was illustrated in another study published in the same year. The study used discovery

For more on SteatoSITE, see
<https://steatosite.com/>

and validation cohorts to predict overall survival after resection of hepatocellular carcinoma.¹⁰⁸ Two deep-learning algorithms were used in the study: one using pathologist-annotated images and one without annotation. Both models had a higher discriminatory power than a score combining all available baseline variables associated with survival. When explainability methods were employed to understand the contribution of the image to outcomes, the tumoural areas most predictive of poor survival were characterised by vascular spaces, a macrotrabecular architectural pattern, and absence of immune infiltration. All these features are histological predictors of poor outcomes; however, hepatitis B virus was the most common aetiology, making it difficult to generalise these findings to other aetiologies.

Deep learning using a weakly supervised multiple-instance learning framework has been used in hepatocellular carcinoma to assess the presence of microvascular invasion, a feature associated with poor prognosis.¹⁰⁹ Visualisation results showed that macrotrabecular architecture with abundant blood sinus, rich tumour stroma, and high intra-tumour heterogeneity were identified as the key features associated with microvascular invasion, whereas the absence of invasion was associated with marked immune infiltration and well differentiated tumours. Pathologist review of regions of interest identified by explainable models is useful for interpreting AI results, and current approaches include saliency maps, concept attribution, and trust scores.²⁰ However, it must be acknowledged that the area of AI explainability is still immature, requiring further development to ensure that explainable models present outputs in a way that enables pathologists to understand the model decision at the user interface.²⁰

Two studies have addressed the grading of hepatocellular carcinoma based on nuclear morphology.^{110,111} The second study used a deep-learning network approach for segmenting nuclei and allowing differentiation of separate nuclei in a way that successfully dealt with overlapping nuclei, a general problem in this field.¹¹¹

Assessing the percentage of viable tumour in a specimen is crucial for evaluating tumour regression following neo-adjuvant therapy and assessing sample suitability for molecular or other studies. Roy and colleagues¹¹² developed a highly effective convolutional autoencoder approach to assess the percentage of viable tumour. This approach is practically useful because assessing viable tumour is a routine histological task that is challenging, subjective, and semiquantitative for histopathologists.¹¹³ Cancer research, in general, is increasingly taking a multiomics approach, and computational pathology has a central role to play in this development.¹¹⁴

Immunotherapy has an increasing role to play in the management of hepatocellular carcinoma. Immune and inflammatory gene signatures can help to predict responsiveness, and AI applied to H&E-stained sections can reliably provide this information. AI has been applied to the prediction of immune modulators in hepatocellular

carcinoma. The authors trained the AI model, using a multicentre dataset from The Cancer Genome Atlas and concluded that application of AI to hepatocellular carcinoma biopsies can act as a biomarker for progression-free survival in patients treated with atezolizumab–bevacizumab.¹¹⁵

Foundation models are a novel and potentially powerful development in AI. These models are trained on very large datasets with a broad range of data rather than on a specific diagnostic task.¹¹⁶ A further development of this principle resulted in the development of vision–language models, in which textual information (eg, pathology diagnoses or entire reports) is paired with the image data in a large model.¹¹⁷ These vision–language models or foundational models in general have produced impressive results in wide-ranging evaluations across various pathology task types and question–answer type evaluations. However, the datasets on which foundation models are trained often have relatively few images of liver disease, and even fewer of non-neoplastic disease;¹¹⁸ hence, further work is needed to evaluate their accuracy and effectiveness in liver pathology.

Liver transplantation

The specialised nature of liver transplantation means that care is often delivered at centralised transplant centres with expert pathologists. For example, in the UK, liver transplantations are performed at seven adult transplant units and three paediatric transplant units.¹¹⁹ Pathology workforce shortages affect liver pathology and can present a challenge in ensuring adequate expert cover for emergency transplantation samples.^{7,120} A national digital pathology system would benefit patients in pretransplantation assessment of their primary disease, peritranplantation evaluation of donor livers for suitability, and post-transplantation graft monitoring. Although systems are being developed and validated in the UK and elsewhere, published evidence is currently unavailable for citation purposes.

Interest in the use of digital pathology and AI for applications across organ transplantation is growing.^{120,121} Within liver disease, quantitation of steatosis in transplant samples has previously been highlighted as an area in which AI would help to speed up assessment.¹²² In 2020, Salvi and colleagues¹²³ described a deep-learning method for steatosis detection in liver transplant samples. Their approach showed a promising accuracy of 97·27% ($\pm 2\cdot71$) for steatosis detection. However, further evaluation on large datasets is required. In 2022, Yu and colleagues¹²⁴ used a deep-learning-based model to segment portal tract regions with an accuracy of 0·89 in liver tissue from patients who had received a liver transplantation. Other groups have also explored the area of transplant steatosis assessment with varying success.^{125,126}

Challenges

Numerous challenges and barriers must be addressed to enable widespread adoption of both digital pathology image analysis and AI (table) and to realise benefits for patients and clinical workflows.

	Examples of reasons for challenges	Solutions
Access to digital pathology technologies	Cost; set-up effort; maintenance; existing infrastructure in information technology; staffing knowledge and resource	Cost reduction over time; increasing global uptake and knowledge; increasing funding for digitisation of health-care workflows; digital research dissemination and education
Access to high-quality diverse datasets for AI development	Set-up effort; data sharing restrictions; clinical system limitations; government and legal restrictions	Open science principles; development of large public datasets; development of multi-institutional digital infrastructure; digital research collaborations
Digital incompatibility	Multiple vendors for scanners, image viewers, and AI tools; existing infrastructure in health information technology	Vendor-neutral solutions; industry collaborations; large-scale digital infrastructure development
Image-quality control	Sectioning or laboratory processing issues; variation among laboratories; scanning artifacts; scanning variation; image compression; variable image quality and compatibility requirements	Digital image quality research; quality control tools and AI; quality control frameworks and standards
Performance and safety concerns of new digital technologies	Gaps in regulatory frameworks to address issues specific to digital products; paucity of research evidence on evaluation and performance in practice	Development of robust digital regulatory frameworks; better research evidence for implementation of digital technologies; rigorous and independent evaluations of new products; evidence and guidance for health-care providers when purchasing new products
Varying availability of guidelines for reporting research and the clinical use of digital technologies	Gaps in existing guidance to address issues specific to digital products; paucity of research evidence and expert consensus	AI-specific reporting guidelines; increasing guidance from professional bodies; growing body of research evidence; guidance from key regulatory bodies

The table presents a summary of key challenges, along with examples of reasons behind these, and solutions to overcome them.^{26–28,33,127–129} AI=artificial intelligence.

Table: An outline of challenges to widespread use of digital pathology and AI, and potential solutions

Access to digital technologies in low-resource settings

Low-income and middle-income countries represent 87% of the world's population, but have access to only a small proportion of global health-care resources.⁸ Shortages of pathologists, skilled laboratory staff, and infrastructure, combined with substantial unmet health needs (in particular, viral hepatitis and consequent cirrhosis and hepatocellular carcinoma), have prompted exploration of digital technologies to address these challenges.

The above challenges are compounded by the high levels of HIV (which can increase the risk of liver diseases) and the increased prevalence of MASLD. However, additional hurdles frequently hinder effective utilisation of digital technologies in these countries. An unreliable power supply, erratic internet connectivity with restricted bandwidth, highly constrained financial resources and purchasing power, and in some regions, political conflict and unrest, all pose unique challenges. Although the cost of purchasing infrastructure for whole-slide imaging remains high, access to telepathology remains an ideal solution to obtain sorely needed specialist pathology expertise for low-resource settings.^{130–132} The application of teleradiology in this setting gives an idea of both the challenges and the scope of what can be achieved. The opportunity to reap huge benefits from AI application to either telepathology or digital pathology in areas of such unmet need has been highlighted along with the benefits that financial investment in these technologies would bring to low-resource settings.^{133,134} Online digital pathology educational resources used for training junior pathologists and for keeping senior pathologists up-to-date is another example of a domain in which the benefits of digital pathology are being realised in low-resource settings.¹³⁴ The potential of AI and digital pathology for health-care providers in this setting has recently been reviewed, and whilst there are many challenges to digital adoption where resources are limited, there are options including access to open-source digital collections and software.¹³⁵

Technical challenges

Once laboratories are in a position to use image analysis, there are other factors affecting the successful development and implementation of AI in clinical use. AI models must be developed on large, diverse, and representative datasets to be robust in clinical settings and avoid bias that could adversely affect real-world accuracy. Obtaining the volume of multinational liver disease data required is a challenge, with insufficient high-quality and easily accessible datasets currently available, particularly for non-neoplastic liver disease. Similarly, there is a paucity of challenge or benchmark datasets that can be used to evaluate and compare AI tools. Initiatives such as bigpicture are attempting to build large digital pathology repositories to facilitate improved access to these data. The liver node of the bigpicture project will host approximately 50 000 whole-slide images of diverse liver pathologies.¹³⁶ Other variables such as the scanner vendor, viewing platform, and the variation between individual laboratories are important considerations when implementing AI tools in terms of the impact on model accuracy and the inclusion of diverse images in datasets.²⁵

Image quality is a challenge for digital liver pathology, especially with the range of special stains that are routinely used. Variable interpretation of liver fibrosis owing to staining variation has previously been identified as an issue.^{66,137} This issue extends beyond liver pathology; a 2021 study reported image-quality issues during the application of a simple image analysis tool to assess the tumour–stroma ratio from digital pathology images.¹³⁸ On using a clinical trial dataset, 33% of cases were accepted as having no image-quality issues and 45% cases had quality issues related to staining. The clinical effect of stain variation in the real world is a complex area, and further work is needed to measure and adapt for it.

Other barriers to the successful use of AI include the difficulty in showing or understanding the link between the

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input data and the output of the AI tool (ie, a shortage of explainability) and a tendency for AI models to perform poorer on real-world data than during experimental evaluations. For example, a study examining the impact of tissue contamination artifacts (commonly seen in clinical practice) on AI models observed a reduction in diagnostic performance across all models.¹³⁹

Errors

Despite the interest and hype surrounding AI applications in pathology, it must be acknowledged that AI introduction has the potential to introduce errors into the diagnostic pathway, and consequences for patients can be substantial. In contrast to the corresponding situation with radiology, digital pathology requires additional steps before the images are subject to examination (owing to tissue processing and slide preparation), with a consequent increase in the probability of errors. Specific sources of errors include difficulty in assessing nuclear morphology (including mitoses) and challenges in examining multiple section planes. There needs to be careful oversight and monitoring by health-care professionals, along with model evaluation before the introduction and adoption of AI in a clinical setting. The approach should centre on patient safety, with appropriate risk-reduction measures in place. Current AI tools are not suitable for unsupervised deployment, and most currently approved AI tools act as a second read alongside pathologist assessment (ie, providing a second opinion rather than an independent diagnosis).¹⁴⁰

AI guidelines

Some initial guidance has been developed for the use of AI in digital pathology, with professional bodies weighing the balance of the rapid progression in this area versus the remaining gaps in evidence around safety concerns. The RCPATH released a position statement to specifically address AI, describing their view and approach to the introduction of AI into clinical practice.¹⁴¹ Similarly, a concept paper on the evaluation of machine learning in pathology was issued by the CAP in 2024 to address the introduction of clinical AI tools.¹⁴² Regulatory frameworks also need to quickly adapt to address the wave of health-AI tools becoming rapidly available for use in clinical practice.^{143–145} Poor reporting of AI studies is prevalent in research, and many studies show methodological flaws and biases.^{146–149} To combat these concerns, AI-specific reporting guidelines have been developed for several study types to improve the quality of reporting of AI research.^{129,149–153}

Education

The role and benefits of digital pathology for medical education have become clear in recent years, with multiple online resources available and accessed by pathologists globally, including Virtual Pathology at the University of Leeds, UK.¹⁵⁴ Many liver pathologists already have some access to digital pathology and use it for external quality assurance, teaching, and online training activities.^{3,120}

Search strategy and selection criteria

Originally, we identified references for this Review by searching PubMed and EMBASE using the search terms “digital pathology”, “histopathology”, “artificial intelligence”, “deep learning”, and “machine learning” on Aug 1, 2022. We also identified research and review articles by searching the authors’ (RG, CM) file collections and through updated searches and article alerts during manuscript drafting. Articles were included if they addressed digital imaging or image analysis or AI techniques with relevance to liver histology and excluded if specific to other subspecialties of histopathology or focused on imaging modalities outside of pathology. We reviewed only the papers published in English. The reference list was finalised on Oct 3, 2025, and generated on the basis of relevance to the reader and representation of the review scope.

Training of the next generation of pathologists will increasingly include the use of digital pathology, and the pathologists of the future will be working with a wider range of digital tools for use in clinical practice.^{128,145} The COVID-19 pandemic highlighted the value of digital pathology for remote working and training.¹⁵⁵ As the availability of digital pathology increases, its full potential within medical education will be realised.

Conclusions

Digital pathology, image analysis, and AI technologies will have an important role in future clinical practice in liver disease. The ability to obtain rapid second opinions, to work remotely, to improve pathologist coverage for urgent transplant samples, and to cooperate and collaborate more readily on a national scale are some examples of how these technologies can be applied. Digital technologies are well established within liver pathology research, and liver pathologists are rapidly gaining access to these tools within their practice. Despite various hurdles, some of which are dependent on appropriate technical infrastructure, resources, and diverse datasets, there are clear areas within liver pathology practice, in which a digital solution would assist in tackling current challenges in laboratories worldwide. However, additional work is needed to evaluate the real-world usefulness, clinical safety, and successful deployment of AI tools in liver pathology.

Contributors

RG conceived the Review. RG, CM, and DT planned the Review. All authors identified relevant references for inclusion in the Review. RG and CM drafted the manuscript. All authors reviewed, revised, and approved the final version of the manuscript. All authors had final responsibility for the decision to submit for publication.

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