Breast Cancer Diagnosis Reimagined: The Rise of Biopsy 2.0 and Artificial Intelligence: A Review

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ABSTRACT

Breast cancer continues to hold the title of most common cancer among females around the world as it remains a significant contributor to cancer-related deaths. The speed and exactness of diagnosis serve as critical determiners for improved results yet standard biopsy procedures such as Core Needle Biopsy (CNB) and Fine Needle Aspiration (FNA) need better specimen acquiring techniques because of their irregular interpretations and slow diagnostic processes. Biopsy 2.0 emerged through artificial intelligence technologies to provide better diagnostic accuracy by integrating Al systems during biopsy evaluation but also guarantees efficient personalized outcomes. Al applications in breast cancer diagnosis span multiple domains. CNN-based deep learning models achieve diagnosis performance like experienced pathologists when they analyze WSIs to diagnose tumors and determine their staging and identify receptor activities. Al systems support current liquid biopsy techniques by analyzing circulating tumor DNA (ctDNA) together with Circulating Tumor Cells (CTCs), which enables early disease detection and proper treatment monitoring as well as prognosis of recurrence. Healthcare providers obtain better risk assessments and create person-specific treatment plans through AI predictive models, which handle clinical information with molecular data. The adoption of new biosystems for clinical practice encounters present barriers due to data prejudice and regulatory constraints, and interpretation barriers, which delay widespread implementation. This investigation explores current developments with clinical importance of Al-based breast cancer biopsy approaches alongside an assessment of Biopsy 2.0 as a potential system to revolutionize oncological testing and prediction.

Keywords: Biopsy 2.0, Breast cancer, Artificial Intelligence, Liquid Biopsy, Histopathology.

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INTRODUCTION

Breast cancer continues to rank as a major worldwide public health issue because it is the primary cancer affecting women, while being the dominant reason behind female cancer deaths. GLOBOCAN 2020 reports that breast cancer generated 2.3 million new cases globally in the year 2020, while resulting in 685,000 deaths, which exceeded lung cancer data. It creates different levels of burden because geographic location outcome affects patients who also face challenges from their socio-economic status and natural genetic structure. The disease demonstrates complex character because molecular heterogeneity combines with diverse clinical manifestations as well as variable treatment outcomes. The extensive range of features in cancer disease makes it imperative to develop exact diagnostic and prognostic tools. Early diagnostic



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precision proves vital to enhance survival outcomes, together with treatment strategies and disease-related health outcomes. For decades, the standard histopathological diagnostic tools for medical diagnosis have been Core Needle Biopsy (CNB) and Fine Needle Aspiration (FNA).3 Advanced diagnostic technologies should be developed urgently because breast tumors hide inside dense breast tissue when mammography scans are performed.⁴ This requirement highlights the need for improvements in challenging diagnostic scenarios. Commercial diagnostic systems undergo digitization at the same moment that the field of breast cancer diagnostics becomes increasingly complex. The diagnostic workflows benefit from Artificial Intelligence (AI) because of Machine Learning (ML) and Deep Learning (DL) algorithm implementations. Extraction of vital clinical information for improved patient health outcomes occurs through artificial intelligence processing of digital histopathological images and radiological scans, together with liquid biopsy details.⁵

When Artificial Intelligence (AI) enters the field of breast cancer diagnosis, it leads to a full transformation of typical medical

diagnostic processes. In health care, artificial intelligence technology provides clear tumor identification across multiple subtypes and ongoing evaluation to predict treatment responses, leading to precise diagnostics and accelerated medical services tailored to each patient. AI systems now evaluate complex molecular data for non-invasive liquid biopsy techniques, which have emerged for continuous disease surveillance. AI technology used in medical diagnostics reduces incorrect diagnosis occurrences and unnecessary biopsy referrals that serve as important factors for enhancing treatment systems and resource allocation.⁶

Ongoing clinical research with proof and validation of AI systems contributes to ensuring positive healthcare delivery system changes due to these technologies. The deployment of artificial intelligence for breast cancer diagnosis creates key regulatory issues, together with trust challenges that need to be resolved. The development of AI systems depends on their ability to operate safely and effectively without biased content, since that creates medical trust throughout the healthcare sector.^{6,7}

The development of automated analysis algorithms that inspect breast images starting from mammograms and ultrasound stands out as a noteworthy advancement in this medical field. Medical image processors use complex data analysis methods and vast datasets to search for small cancer indicators, which develop enhanced diagnostic support tools for radiologists. DeepSeeNet, along with other AI models, demonstrates capabilities for automatically diagnosing breast cancer severity through imaging data, which leads to quicker and better diagnosis results. AI demonstrates efficiency in processing complex visual data through its ability to measure and segment lesions according to developed systems such as those used for drusen segmentation in retinal imaging. Reference of the segmentation in retinal imaging.

Traditional Diagnostic Methods and their Limitations

Mammography is a traditional method of breast cancer screening, but there are limits to its effectiveness, particularly in women with dense breast tissue. Early detection is likely to be compromised in these women, which may lead to delayed treatment. AI algorithms are being developed to assist radiologists somewhat in their classification after conventional mammograms. AI can help radiologists quickly sift through massive amounts, categorising vast data, and detect patterns that may not be visible to the naked eye or effectively highlight an abnormality in dense breast tissue. AI represents the chance to create uniformity of image

Table 1: Difference between traditional biopsy and Al-enhanced biopsy.

Traditional Biopsy		Al-Enhanced Biopsy
Invasiveness	Involves surgical or needle. procedures (e.g. core needle biopsy).	Utilizes non-invasive methods like liquid biopsy and advanced imaging.
Sample Type	Requires tissue extraction.	Analyzes circulating tumor DNA (ctDNA), Circulating Tumor Cells (CTCs) or imaging data.
Turnaround Time	Several days to weeks.	Potentially faster due to automatized analysis.
Diagnostic Accuracy	High, but subject to human error and inter-observer variability.	Enhanced accuracy with AI algorithms reducing variability and improving detection rates.
Risk of Complications	Bleeding, infection, and discomfort.	Minimal, especially with non-invasive techniques.
Cost	Generally higher due to surgical procedures and pathology analysis.	Potentially lower in the long term with streamlined processes and reduced need for invasive procedures.
Data Utilization	Limited to physical samples.	Integrates multi-model data for comprehensive analysis.
Personalization	Standardized approach.	Enables personalized treatment plans based on predictive modeling and patient-specific data.
Regulatory approval	Established protocols and widespread clinical acceptance.	Emerging technologies with ongoing validation and regulatory review.
Clinical implementation	Widely implemented in clinical practice.	Gradual adoption with pilot programs in select institutions.

interpretation, to potentially reduce false negatives, and improve confidence in a diagnosis, leading to improved patient outcomes.⁸

While imaging assessment is essential, particularly in cases identified by an AI tool, tissue sampling is still the only way to definitively diagnose breast cancer. Core Needle Biopsy (CNB) and Fine Needle Aspiration (FNA) are the most utilized sampling methods for breast cancer sampling. Each method has unique applications. CNB utilizes a larger gauge needle to obtain cylindrical tissue samples whilst maintaining the overall tissue architecture for histological processing, while FNA uses a small gauge needle to extract cell material from the breast and is perceived to minimize invasiveness and time to diagnosis.¹¹

Although they are commonly used, they have significant limitations such as sampling error (if the needle does not obtain material from the most representative portion of the lesion, there will be a false negative), inadequate or non-diagnostic samples are more common in FNA than in core biopsy.¹² These inadequacies will lead to a possible delay in diagnosis and repeat procedures and the variability in interpretation between pathologists becomes another limitation. These techniques carry a small risk of complications including bleeding, infection, and discomfort.¹³

These limitations highlight the need for ongoing refinement in biopsy techniques and support the growing interest in integrating AI not only in imaging interpretation but also in procedural

Suspicious lump detected via clinical examination



Biopsy ordered by physician



Tissue sample collected



Histological slide prepared



Slide digitized into whole slide images



AI analysis of digital slides



Prediction of biomarkers and tumor characteristics



Pathologist reviews AI findings



Diagnostic report generated



Oncologist plans treatment based on diagnosis

Flowchart 1: Workflow of biopsy 2.0.

planning, Table 1 shows the Major differences between traditional biopsy and AI-enhanced biopsy. ¹⁴ AI could assist in optimizing needle placement, reducing variability, and potentially predicting the most diagnostically useful regions to sample, thereby improving diagnostic yield and reducing the burden of repeat procedures. ¹⁵

Al Biopsy 2.0: Redefining Breast Cancer Diagnostics

Flow chart 1 AI Biopsy 2.0, an innovative innovation of Artificial Intelligence (AI) technologies to breast cancer diagnosis and management by efficient implementation of biopsy cases through utilizing machine learning algorithms. One of the most significant advantages is that AI tools can address most of the biopsy cases in less than a minute, ultimately facilitating clinical and patient decision-making.¹⁶ Biopsy 2.0 pushes beyond static invasive tissue sampling by employing various technologies, including next-generation sequencing, liquid biopsies (circulating tumour DNA and exosomes), and other data analytics driven by AI. These technologies offer real-time insight into the biology of any given tumour and mitigate the spatiotemporal limitations of traditional core needle or fine needle aspiration biopsies.¹⁷ Real-time accessibility and analytics allow for an innovative integration which will allow for longitudinal monitoring of the evolution of tumours, earlier opportunities for intervention when relapse occurs, and potentially more accurate therapy selection to the molecular profile of each patient.¹⁸

The concept of a virtual biopsy is a key innovation in this landscape. The goal of the virtual biopsy is to replace or augment traditional physical biopsies, capturing diagnostic information from non-invasive imaging and data analysis to reduce patient discomfort and risk while undergoing procedures.¹⁹ Virtual biopsies leverage AI to analyse imaging information and other biomarkers to make inferences about tumours without performing an invasive physical tissue removal biopsy.²⁰

Additionally, AI models are being developed to estimate breast cancer risk based on a composite of lifestyle, genetic susceptibility, and environmental exposures. Together, these advancements are leading to a faster, more objective, less invasive, and better customized diagnosis of breast cancer, which is a pivotal step forward in precision oncology.²¹

Al-Assisted Diagnostic Tools in Breast Cancer Detection

Artificial Intelligence (AI) is quickly changing the way breast cancer is diagnosed, providing tools that improve how fast, accurate, and consistent the diagnosis of the disease can be. AI-assisted diagnostic systems apply algorithms based on deep learning and pattern recognition to analyse imaging, histopathological slides, and genomic data significantly faster than a human can using traditional methods.²²

Recent efforts with AI-assisted diagnostic tools demonstrate significant potential to improve diagnostic capabilities for breast cancer, more accurate predictions, and earlier diagnosis of disease. The AI systems are trained to detect medical imaging abnormalities by identifying slight variations or changes that may not be readily identifiable by human visual recognition, resulting in more precise and accurate diagnostic capabilities by reducing the variability between observers. For example, a new AI-based method was able to diagnose breast cancers very early, virtually giving a chance for treatment before the disease had progressed to even stage 0.²³ There are benefits not only for survival with early detection, but it opens the opportunity to less invasive and more targeted treatment.

For patients with low Tumour-Infiltrating Lymphocyte (TIL) results, this technology is beneficial by keeping them from being overtreated by their standard assessment protocol. By using Artificial Intelligence (AI) to evaluate tumour microenvironments, clinicians can avoid unnecessary radiotherapy with the intention of minimizing the side effects of treatment and improving quality of life. AI is also being utilized to personalize risk evaluation by combining patient demographic information, genetics and clinical information and imaging information together. The layered analysis provides a pathway for precision medicine to work, as oncologists will have the ability to tailor screening and treatment selections for individual patients.

Al in Histological Image Analysis

The shift from using traditional glass slides to utilizing digital pathology has paved the way for implementing artificial intelligence in histological analysis.²⁶ Whole slide imaging affords pathologists the overall imaging of persistent utilization of tissue samples, and subsequent viewing, annotating, and analysis using computational tools. In addition, this type of imaging is suitable for the application of AI models, specifically deep learning models, which can aid in performing complex tasks such as tumour detection, grading, and the prediction of molecular features.²⁷

AI-based histological image analysis has notable applications in breast cancer diagnostics. Deep learning algorithms are suitable for both automation and semi-automation of histological images. Deep learning algorithms can be trained to recognize very subtle morphological patterns within tissue sections and contribute significantly to identifying malignant features that may be missed during manual review. These algorithms allow for improved diagnostic accuracy, decreased inter-observer variability, and allow for more standardized assessments among institutions.²⁸

AI based systems may even be able to predict clinically valuable biomarkers, including hormone receptor status and HER2 expression from histological images with the potential for fewer immunohistochemical stains. AI systems can identify tumour-infiltrating lymphocytes, which are valuable prognostic markers especially in the context of triple-negative breast cancer.²⁹ It seems plausible that with the ongoing, increased incorporation of digital pathology, AI will form a greater part of the histopathological workflow in the future, allowing for more reliable and efficient diagnoses and support for precision oncology. A push for expanding and more consistent use of AI can help speed our histopathological workflows and lead to improvements in the diagnosis of breast cancers, especially where there are more complex and atypical patterns.³⁰

Diagnostic Decision Support Systems

Integrating AI into diagnostic decision support systems has improved the accuracy of breast cancer diagnoses. At the same time, AI analysis of biopsies-maintained sensitivity while reducing biopsies by 27.8% and false positives by 37.3%.31 This is beneficial for minimizing patient suffering, avoiding needless invasive procedures, and making certain that medical resources are optimally utilized in healthcare systems. AI systems are being utilized in actual practice settings as well. Google Health's AI model, currently being piloted in remote hospitals in Thailand and India, has been proven to be an effective, low-cost solution for breast cancer screening in resource-poor settings.³² Clinicians are being augmented with AI systems that assist in the detection of suspicious lesions and triage patients who need urgent care. One recent clinical review concluded that AI does a good job at spotting politically important high-risk findings and further adds to efforts to improve early detection.33 Algorithms that combine imaging and histopathological features with AI achieve diagnostic accuracy of 81% and 93% of the time.³⁴ These systems provide error reduction of the diagnostic pathway and improve

diagnostic workflow, including within screening or routine pathology work. As AI continues to develop, the opportunity for decision support is pivotal.³⁵

Al for Predictive and Prognostic Modelling in Breast Cancer

In breast cancer management, the accurate prediction of treatment response, recurrence or survival outcome is critical in developing individualized treatment plans. Traditional prognostic models (for example, Nottingham) are beneficial for practicality; however, they have limitations, including their model is based on a fixed set of clinico-pathologic features, and has statistical properties that are linear. These models fail to capture the biological complexity and heterogeneity that make breast cancer unique. The survival outcome is critical in developing individualized treatment plans.

Artificial Intelligence (AI), and more specifically Machine Learning (ML) and Deep Learning (DL), can be highly disruptive in overcoming the limitations of traditional models of breast cancer predictive modelling based on a fixed number of variables. AI models can be used to model non-linear associations in datasets that span multiple modalities, including genomics, histopathology, imaging, and electronic health records. Because these models rely on processing large amounts of what may be considered noise, they are able to identify relationships that might otherwise be unnoticed, allowing for a more accurate prognosis and improved prediction of individual tumour response to treatments. AI algorithms have, for instance, been developed to predict recurrence likelihood and overall survival rates more accurately than traditional tools provide. Such tools allow better patient-centred clinical decision-making.³⁸

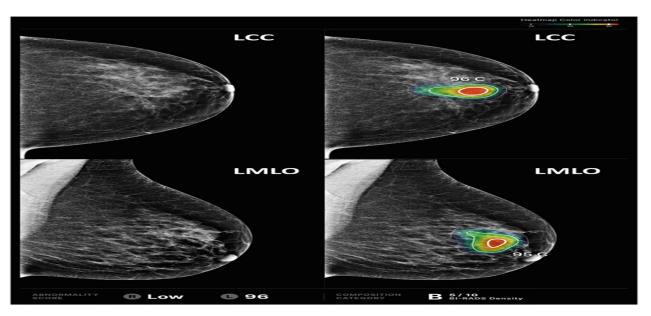


Figure 1: The figures show the original two views (LCC and LMLO), as well as the AI outputs generated using the Lunit INSIGHT MMG (Lunit Inc.). These AI outputs display abnormality scores to indicate a cancerous lesion and heat maps for localization. A density score was provided, according to the BI-RADS category on a scale of 1-10.

LCC = Left Craniocaudal; LMLO = Left Mediolateral Oblique; AI = Artificial Intelligence; MMG = Mammography; BI-RADS = Breast Imaging Reporting and Data System.

In the "real world", AI algorithms are used in conjunction with data analysis to help clinicians assess outcomes in complex scenarios, including histopathological images, radiographic scans, and molecular markers from liquid biopsies. For instance, Figure 1 gives the original images and AI-generated outputs for LCC and LMLO. Some oncology centres have adopted pathology platforms that utilize AI to conduct 95% of the work to classify tumour subtypes for clinicians. This can lead to faster and more confident decisions.

Regulatory and Ethical Considerations

Breast cancer diagnosis will advance through ongoing development and the combination of Artificial Intelligence (AI) throughout diagnostic processes. To better understand tumour biology at the individual level, research advances will result in hybrid AI systems that combine different diagnostic data, such as radiological imaging with histopathological data and genomic information with clinical records. The combined diagnostic systems work toward enhancing accurate prognoses while dividing patient risks and foreseeing therapy results to eventually drive precise disease treatment plans. Future demands the creation of AI models that provide explanations for medical staff to understand the reasoning behind algorithmic decisions. The ultimate requirement for clinical adoption, together with patient safety, depends on clear transparency. The development of federated learning models, which conduct AI training across distinct centers through data retention at source positions, is a solution for maintaining patient privacy and enhancing data diversity potential.39

AI tools need proper validation testing when used in genuine medical practices to achieve clinical success. Future trials involving multiple medical facilities will serve as the primary method to investigate both clinical efficiency and economic value, as well as treatment results for patients. Regulations must adapt into standards that provide decisive evaluations for AI algorithms while they resolve questions related to safety, reliability together with ethical aspects.⁴⁰

FUTURE DIRECTIONS

Breast cancer diagnosis will advance through ongoing development and the combination of Artificial Intelligence (AI) throughout diagnostic processes. Advances in research will result in multimodal AI systems that combine genomic information, histopathological data, radiological images, and clinical records to provide a biological understanding of tumours specific to each individual.

These united strategies help doctors identify illnesses better while dividing patient risks and foreseeing treatment outcomes to achieve individual treatment strategies. Future demands the creation of AI models that provide explanations for medical staff to understand the reasoning behind algorithmic decisions. The

ultimate requirement for clinical adoption, together with patient safety, depends on clear transparency. The implementation of federated learning systems enables AI training across various medical institutions while keeping patient information secure, thus allowing the improvement of diverse dataset access. Real-world clinical environments require validation as the main important direction for AI tools.

Future trials involving multiple medical facilities will serve as the primary method to investigate both clinical efficiency and economic value, as well as treatment results for patients. Regulatory systems must develop assessment standards that analyze AI systems thoroughly, so they address quality and ethics together with safety and reliability requirements. Medical AI systems would become more relevant in the context of evolving clinical procedures if they were to continuously improve through incremental learning of new data. Such systems need protective measures to stop clinical errors from getting worse with time. Making sure AI technologies are available to everyone equitably presents the main problem area.⁴¹

CONCLUSION

Artificial intelligence has brought significant progress to breast cancer diagnostics in the field of oncological care. Artificial intelligence (AI)-enabled breast cancer biopsy procedures comply with Biopsy 2.0 guidelines, which improve accuracy and yield trustworthy diagnosis results with optimized workflows from interpreted Liquid Biopsy data and pathologic image analysis results. These procedures also support research on predictive modelling. The implementation of AI solutions during pathologic workflows enables healthcare professionals to make data-based decisions that determine timely patient treatment results. The ability of AI to analyze complex data patterns results in improved tumor identification, enabling ongoing real-time risk assessment and the creation of customized treatment plans. AI models have the remarkable capacity to detect molecular breakdowns that alert to a condition relapse before clinical symptoms appear, thereby identifying early disease indicators within minimally invasive testing procedures. Widespread use of AI in breast cancer diagnosis requires the resolution of four major challenges, which include biased algorithms and data format discrepancies and ethical issues together with proper regulatory oversight. For AI to function as a helpful assistant in medical settings, healthcare professionals require transparent models with explainable algorithms alongside equal chances for diverse patient groups to train their systems.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

CNB: Core Needle Biopsy; **FNA:** Fine Needle Biopsy; **CTC:** Circulating Tumor Cell; **ML:** Machine Learning; **DL:** Deep Learning; **AI:** Artificial Intelligence.

SUMMARY

Artificial Intelligence is helping improve how images and biopsies for breast cancer are analyzed. AI-supported tools are making it possible to find cancerous cells in biopsies faster and with less error, while also making mammogram and MRI readings more accurate for radiologists. They help lower the risk of misdiagnosis, enable early detection and predict how likely a treatment will be successful and when the cancer may return. Nevertheless, dealing with challenge areas such as algorithm bias, clinical integration and data transparency is necessary before many can use them.

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