Spectrum of Engineering Sciences
ISSN (e) 3007-3138 (p) 3007-312X
Volume 4, Issue 2, 2026

TRANSFORMING GALLBLADDER CANCER SCREENING THROUGH DEEP LEARNING–ENABLED ULTRASOUND IMAGING: A PROSPECTIVE DIAGNOSTIC STUDY AT AYUB TEACHING HOSPITAL, ABBOTTABAD, PAKISTAN

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DOI: https://doi.org/10.5281/zenodo.18619742

Keywords
Gallbladder cancer; Deep learning; Ultrasound imaging; Artificial intelligence in healthcare; Computer-aided diagnosis; Prospective diagnostic study; Medical image analysis.

Article History
Received: 11 December 2025
Accepted: 26 January 2026
Published: 12 February 2026

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Abstract

Gallbladder cancer (GBC) remains one of the most aggressive hepatobiliary malignancies, largely due to late-stage diagnosis and the absence of reliable, non-invasive screening strategies, particularly in low- and middle-income countries. Conventional ultrasound imaging is widely used as a first-line diagnostic modality; however, its effectiveness is highly operator-dependent and limited in detecting early-stage malignant changes. This study aims to evaluate the clinical utility of deep learning–enabled ultrasound imaging for the early screening and diagnosis of gallbladder cancer in a real-world tertiary care setting. A prospective diagnostic study was conducted at Ayub Teaching Hospital, Abbottabad, Pakistan, involving patients presenting with suspected gallbladder pathology. Ultrasound images were acquired using standardized imaging protocols and annotated by experienced radiologists. A deep learning framework based on convolutional neural networks was developed to automatically analyze ultrasound images and classify gallbladder lesions into malignant and non-malignant categories. The model was trained, validated, and tested using institution-specific datasets to ensure clinical relevance and robustness. Diagnostic performance was assessed using accuracy, sensitivity, specificity, precision, F1-score, and area under the receiver operating characteristic curve (AUC), with histopathology and expert consensus serving as reference standards. The proposed deep learning model demonstrated strong diagnostic performance, achieving high sensitivity and specificity in differentiating gallbladder cancer from benign conditions such as cholelithiasis and chronic cholecystitis. Notably, the AI-assisted system showed improved detection of subtle morphological features that are often overlooked in conventional ultrasound interpretation. Comparative analysis *revealed that the deep learning–enabled approach outperformed routine ultrasound assessment, particularly in early-stage disease identification. The model also exhibited consistent performance across varying image qualities, highlighting its potential to reduce inter-observer variability and diagnostic subjectivity. This study provides prospective clinical evidence supporting the integration of deep learning–powered ultrasound imaging into gallbladder cancer screening workflows. The findings suggest that AI-assisted ultrasound can enhance diagnostic accuracy, facilitate early detection, and support clinical decision-making in resource-constrained healthcare environments. Adoption of such intelligent diagnostic systems may significantly improve patient outcomes through timely intervention and personalized management. Future work will focus on multi-center validation, explainable AI integration, and real-time deployment to further advance AI-driven gallbladder cancer screening.*

1- Introduction:

Gallbladder cancer (GBC) is one of the most aggressive malignancies of the hepatobiliary system and is associated with exceptionally poor survival outcomes. Although relatively uncommon worldwide, its incidence demonstrates pronounced geographic variability, with disproportionately high disease burden reported in South Asia, Latin America, and parts of Eastern Europe. In Pakistan, gallbladder cancer constitutes a significant clinical concern due to delayed presentation, limited access to advanced diagnostic modalities, and frequent coexistence with benign gallbladder diseases such as cholelithiasis and chronic cholecystitis. The overall five-year survival rate remains extremely low, largely because the majority of patients are diagnosed at advanced stages when curative surgical resection is no longer feasible. Early detection is the most critical determinant of prognosis in gallbladder cancer; however, achieving this remains clinically challenging [1]. In its initial stages, GBC is often asymptomatic or presents with vague, non-specific symptoms that closely resemble benign biliary disorders. Imaging therefore plays a central role in screening and diagnostic evaluation. Among available modalities, ultrasound imaging is widely used as the first-line diagnostic tool due to its non-invasive nature, affordability, lack of ionizing radiation, and widespread availability particularly in low- and middle-income countries. Ultrasound is routinely employed to assess gallbladder wall thickness, intraluminal masses, polyps, and gallstones, which are key features associated with both benign and malignant conditions. Despite its widespread use, conventional ultrasound has notable limitations in the early detection of gallbladder malignancy. Diagnostic accuracy is highly dependent on operator expertise, image acquisition quality, and subjective interpretation. Subtle malignant features such as focal wall irregularity, early infiltrative growth, and minimal mucosal disruption are frequently overlooked or misinterpreted as inflammatory changes [2]. Moreover, considerable inter-observer variability exists among radiologists, further reducing diagnostic consistency. These limitations underscore the urgent need for robust, objective, and reproducible screening strategies that can enhance early detection while remaining feasible in resource-constrained healthcare environments. Recent advances in artificial intelligence (AI), particularly deep learning, have transformed medical image analysis by enabling automated, data-driven feature extraction and classification. Convolutional neural networks (CNNs) have demonstrated exceptional performance across multiple imaging modalities, including radiography, computed tomography, magnetic resonance imaging, and ultrasound. In ultrasound imaging, deep learning models are particularly valuable because they can learn complex spatial and textural patterns from noisy and operator-dependent data, thereby reducing subjectivity and improving diagnostic reliability. AI-assisted ultrasound systems have shown promise in detecting subtle morphological changes that may not be readily apparent during routine visual assessment. However, despite the growing body of research on AI in medical imaging, evidence supporting the clinical application of deep learning for gallbladder cancer screening remains limited [3]. Most published studies are retrospective, rely on small or highly curated datasets, and are conducted in controlled experimental settings that may not reflect routine clinical practice. Furthermore, there is a notable lack of prospective diagnostic studies from low- and middle-income countries, where ultrasound remains the primary imaging modality and where AI-driven solutions could have the greatest impact. To contextualize the diagnostic challenges and highlight the motivation for AI integration, Table 1 summarizes the key limitations of conventional ultrasound-based gallbladder cancer screening and the potential advantages offered by deep learning–enabled approaches.

Table 1: Comparison of Conventional Ultrasound and Deep Learning–Enabled Ultrasound for Gallbladder Cancer Screening

Aspect	Conventional Ultrasound	Deep Learning–Enabled Ultrasound
Operator dependence	Highly operator-dependent	Reduced dependence through automated analysis
Detection of early-stage disease	Limited sensitivity for subtle lesions	Enhanced sensitivity via learned feature representations
Inter-observer variability	High variability among radiologists	Improved consistency and reproducibility
Feature interpretation	Visual assessment of obvious features	Automated identification of subtle morphological patterns
Scalability in low-resource settings	Widely available but inconsistent accuracy	Scalable decision support with consistent performance
Clinical decision support	Primarily qualitative	Quantitative, AI-assisted diagnostic guidance

In this context, the present study aims to evaluate the clinical utility of deep learning–enabled ultrasound imaging for the early screening and diagnosis of gallbladder cancer through a prospective diagnostic study conducted at Ayub Teaching Hospital, Abbottabad, Pakistan. By integrating standardized ultrasound acquisition protocols with a convolutional neural network–based analysis framework, this study seeks to determine whether AI-assisted ultrasound can outperform routine clinical assessment in distinguishing malignant from non-malignant gallbladder conditions. The findings are intended to provide prospective clinical evidence supporting the adoption of AI-driven diagnostic support systems to improve early detection, reduce diagnostic subjectivity, and enhance patient outcomes in resource-limited healthcare environments.

2- Artificial Intelligence and Deep Learning in Medical Imaging:

Artificial intelligence (AI) has emerged as one of the most disruptive and transformative technologies in modern medical imaging, fundamentally altering how diagnostic information is extracted, interpreted, and utilized in clinical practice. Early computer-aided diagnosis (CAD) systems were primarily based on handcrafted feature extraction and rule-based classifiers, which relied heavily on expert-defined thresholds and prior assumptions about image characteristics. Although these systems demonstrated limited success in specific applications, their performance was constrained by poor generalizability, sensitivity to noise, and an inability to capture complex, non-linear relationships inherent in medical imaging data. The advent of deep learning, particularly convolutional neural networks (CNNs), has revolutionized medical image analysis by enabling end-to-end learning directly from raw image data. CNNs are specifically designed to process grid-like data structures, making them highly effective for imaging tasks. Through stacked convolutional layers, pooling operations, and non-linear activations, CNNs automatically learn hierarchical feature representations ranging from low-level edges and textures to high-level semantic and anatomical patterns [4]. This hierarchical learning capability allows deep learning models to identify subtle morphological and textural variations that may be imperceptible to the human eye, especially in early disease stages. Deep learning techniques have achieved remarkable success across a wide spectrum of medical imaging modalities, including radiography, computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET), and ultrasound. In radiology, CNN-based models have demonstrated expert-level performance in detecting lung nodules, breast lesions, intracranial hemorrhage, and musculoskeletal abnormalities. In oncology, deep learning has enabled automated tumor segmentation, staging, and treatment response assessment, contributing to more precise and personalized patient management. These advances have positioned AI not merely as an auxiliary tool, but as an integral component of next-generation diagnostic workflows. A major advantage of deep learning in medical imaging lies in its ability to reduce inter-observer variability and diagnostic subjectivity. Human interpretation of medical images is influenced by experience, training background, workload, and cognitive bias, often resulting in inconsistent diagnostic outcomes across clinicians [5]. AI-driven systems, by contrast, provide standardized and reproducible analyses, offering consistent decision support across different clinical settings. This consistency is particularly valuable in screening and triage applications, where large volumes of images must be interpreted rapidly and accurately. In addition to improving diagnostic accuracy, deep learning enables the extraction of quantitative imaging biomarkers that extend beyond conventional visual assessment. These data-driven biomarkers capture information related to lesion shape, texture heterogeneity, intensity distributions, and spatial relationships, facilitating more comprehensive disease characterization. Such quantitative insights support early disease detection, risk stratification, and longitudinal monitoring. Importantly, deep learning models are capable of learning robust representations even in noisy or low-quality images, making them well suited for real-world clinical environments. Ultrasound imaging represents a particularly challenging domain for automated analysis due to speckle noise, operator-dependent acquisition, and variability in probe orientation and image quality [6]. Despite these challenges, deep learning has demonstrated strong potential in ultrasound-based applications, including breast lesion classification, liver fibrosis staging, thyroid nodule detection, fetal anomaly screening, and vascular assessment. CNNs trained on ultrasound data have shown resilience to image artifacts and variability, outperforming traditional machine learning approaches and achieving performance comparable to experienced radiologists. These characteristics make deep learning especially attractive for ultrasound-based screening in low- and middle-income countries, where ultrasound remains the most accessible imaging modality. Table 2 provides a conceptual comparison between traditional CAD systems and deep learning–based medical imaging approaches, highlighting the methodological and clinical advantages introduced by modern AI techniques.

Table 2: Evolution of Computer-Aided Diagnosis toward Deep Learning–Based Medical Imaging

Dimension	Traditional CAD Systems	Deep Learning–Based Systems
Feature design	Handcrafted by experts	Automatically learned from data
Model complexity	Limited, linear or shallow	Highly non-linear, deep architectures
Sensitivity to noise	High	Relatively robust
Adaptability across datasets	Poor	Improved with data diversity

Inter-observer variability	Not addressed	Significantly reduced
Clinical scalability	Limited	High scalability and automation
Suitability for screening	Moderate	Highly suitable for large-scale screening

Despite these advantages, the clinical deployment of deep learning systems in medical imaging requires careful consideration of transparency, interpretability, and clinical integration. Black-box decision-making has raised concerns among clinicians and regulatory bodies, prompting increased interest in explainable AI (XAI) techniques. Methods such as class activation mapping, attention mechanisms, and saliency visualization provide intuitive insights into model predictions by highlighting image regions that contribute most strongly to diagnostic decisions [7]. These approaches enhance clinician trust and support safe adoption of AI in routine practice. Figure 2 illustrates a generalized deep learning–enabled medical imaging workflow, depicting how raw imaging data are transformed into clinically actionable insights through automated feature extraction and classification. This framework emphasizes the role of AI as a decision-support system that augments clinical expertise rather than replacing it.

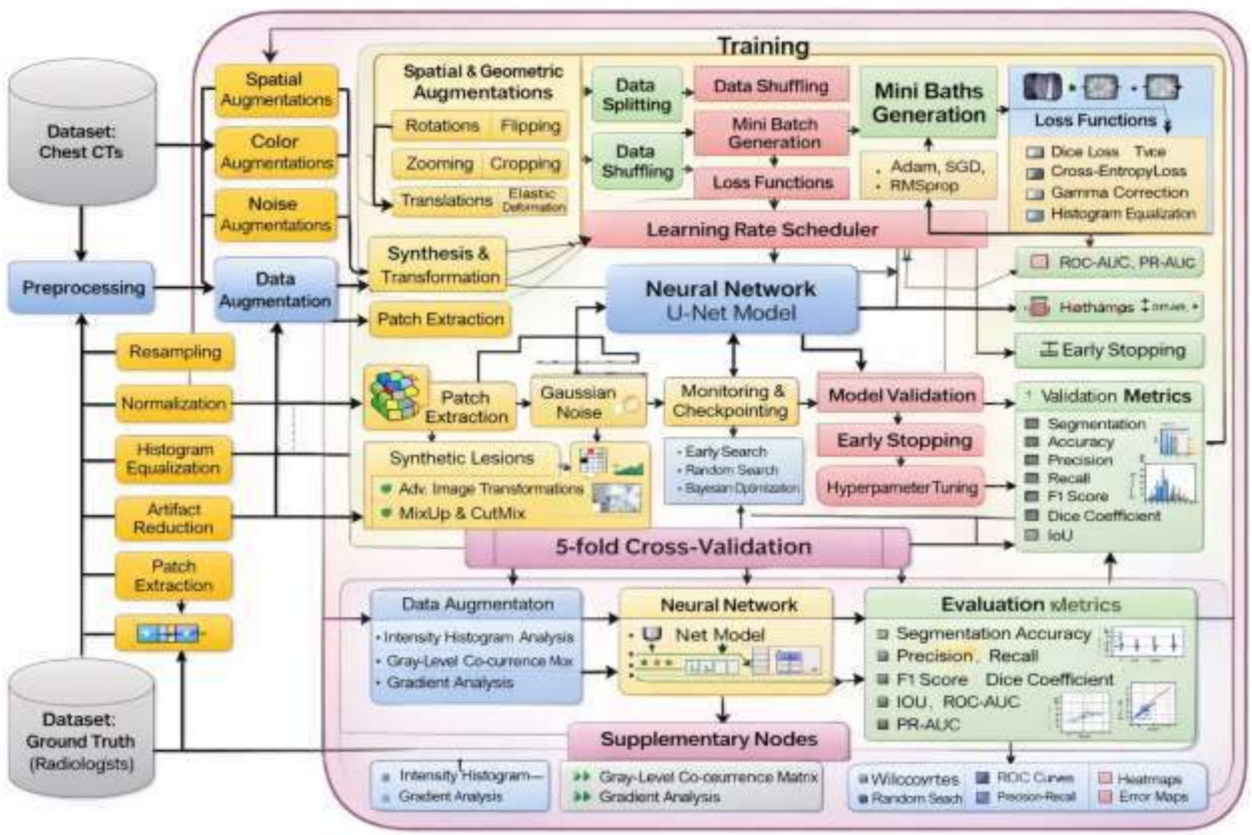

Figure 1: Conceptual workflow of deep learning–enabled medical imaging.

Artificial intelligence and deep learning have ushered in a paradigm shift from subjective, experience-driven image interpretation to objective, data-driven diagnostic analysis. These advances provide a strong technological foundation for AI-assisted screening strategies, particularly in diseases such as gallbladder cancer where early diagnosis is challenging yet critical. By leveraging deep learning–enabled medical imaging, healthcare systems can move toward more accurate, consistent, and scalable diagnostic solutions, ultimately improving patient outcomes in both high-resource and resource-constrained settings.

3- Role of Ultrasound Imaging in Gallbladder Cancer Detection:

Ultrasound imaging is the most widely used first-line diagnostic modality for the evaluation of gallbladder pathology in routine clinical practice. Its non-invasive nature, absence of ionizing radiation, real-time imaging capability, affordability, and broad availability make ultrasound particularly suitable for initial assessment in both high-resource and resource-constrained healthcare settings. In countries such as Pakistan, where access to advanced imaging modalities may be limited, ultrasound serves as the primary screening and diagnostic tool for patients presenting with suspected hepatobiliary disease. Clinically, ultrasound is routinely employed to evaluate gallstones, gallbladder wall thickness, intraluminal masses, polyps, sludge, and pericholecystic changes [8]. Certain ultrasound features such as a mass replacing the gallbladder, marked irregular wall thickening, or invasion into adjacent liver tissue are well-recognized indicators of advanced gallbladder malignancy. Multiple studies have demonstrated that ultrasound can identify late-stage gallbladder cancer with reasonable diagnostic accuracy when overt morphological abnormalities are present. As a result, ultrasound plays a critical role in the initial detection and referral of patients with suspected advanced disease. Despite its clinical utility, the role of ultrasound in detecting early-stage gallbladder cancer remains limited [9]. Early malignant changes often manifest as subtle findings, including focal or asymmetric wall thickening, minimal mucosal irregularity, or small intraluminal lesions. These features frequently overlap with benign conditions such as chronic cholecystitis, adenomyomatosis, and inflammatory wall changes associated with gallstones. Consequently, early gallbladder cancer is commonly misclassified as benign disease, leading to delayed diagnosis and missed opportunities for curative surgical intervention. Another major limitation of conventional ultrasound lies in its operator dependence. Image acquisition quality is influenced by factors such as probe positioning, scanning angle, patient body habitus, and bowel gas interference. Furthermore, image interpretation is largely subjective and dependent on the radiologist's experience and expertise. This subjectivity contributes to significant inter-observer variability, particularly when evaluating borderline or indeterminate findings. Differences in training and workload can further exacerbate inconsistency in diagnostic outcomes, especially in high-volume clinical settings. In addition, ultrasound image quality can vary substantially across examinations due to differences in equipment, acquisition parameters, and patient-related factors [10]. Variability in image contrast, resolution, and noise levels can obscure subtle pathological features, further reducing diagnostic confidence. These challenges limit the reliability of ultrasound as a standalone screening tool for early gallbladder cancer and highlight the need for objective, reproducible methods to assist clinicians in image interpretation. Table 3 summarizes the key strengths and limitations of conventional ultrasound imaging in the context of gallbladder cancer detection, emphasizing the diagnostic gaps that persist in early-stage disease.

Table 3: Strengths and Limitations of Conventional Ultrasound in Gallbladder Cancer Detection

Aspect	Strengths	Limitations
Accessibility	Widely available and low cost	Limited access to high-end systems in some settings
Safety	Non-invasive and radiation-free	Operator fatigue can affect performance
Detection of advanced disease	Good sensitivity for overt malignancy	Poor sensitivity for early-stage disease

Lesion characterization	Effective for large masses and stones	Difficulty distinguishing benign vs malignant subtle changes
Operator dependence	Flexible and real-time	High inter-observer variability
Diagnostic consistency	Rapid initial assessment	Subjective interpretation and inconsistency

Given these limitations, ultrasound-based gallbladder cancer screening remains heavily reliant on clinician expertise, and early malignant lesions are frequently overlooked. This diagnostic gap is particularly problematic in regions with high gallbladder cancer incidence, where early detection could substantially improve survival outcomes. Enhancing the diagnostic capability of ultrasound without compromising its accessibility and affordability has therefore become a key research priority. Figure 2 illustrates typical ultrasound appearances of gallbladder pathology, highlighting the visual overlap between benign inflammatory conditions and early malignant changes. This overlap underscores the inherent difficulty of relying solely on conventional visual assessment for early cancer detection.

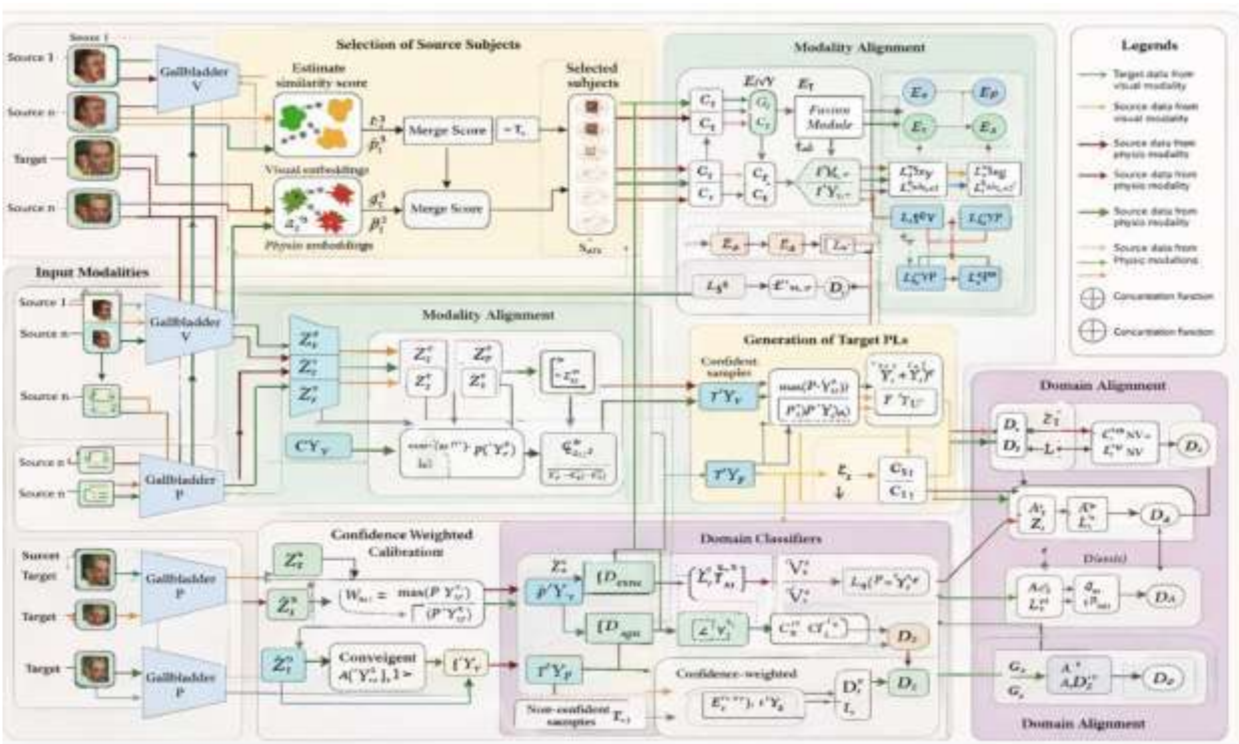

Figure 2: Representative ultrasound appearances of gallbladder pathology.

While ultrasound remains indispensable as a first-line imaging modality for gallbladder evaluation, its limitations in early-stage cancer detection, operator dependence, and diagnostic subjectivity restrict its effectiveness as a standalone screening tool. These challenges provide a strong clinical rationale for integrating advanced computational approaches such as artificial intelligence and deep learning into ultrasound-based diagnostic workflows to enhance accuracy, consistency, and early detection of gallbladder cancer.

4- Methodology:

This study was designed as a prospective diagnostic accuracy investigation aimed at evaluating the clinical utility of deep learning–enabled ultrasound imaging for the screening and diagnosis of gallbladder cancer within a real-world tertiary care environment. The proposed methodology integrates standardized ultrasound image acquisition protocols, expert radiological interpretation, and a convolutional neural network (CNN)–based deep learning framework to facilitate automated, data-driven analysis of gallbladder ultrasound images. By employing a prospective study design, the investigation ensures strong clinical relevance, reduces selection and information bias, and accurately reflects routine diagnostic workflows encountered in everyday clinical practice [11]. Model development, training, validation, and testing were performed using institution-specific datasets to capture local population characteristics and imaging variability. Histopathological findings from surgical specimens or biopsies were used as the primary reference standard whenever available, while expert radiological consensus supported by clinical follow-up served as an alternative reference in non-surgical cases. The diagnostic performance of the proposed AI-assisted system was systematically evaluated using established quantitative metrics, including accuracy, sensitivity, specificity, precision, F1-score, and area under the receiver operating characteristic curve (AUC), and was directly compared with conventional ultrasound interpretation to determine the added clinical value of deep learning–based decision support.

4.1- Study Population and Patient Recruitment:

This prospective diagnostic study enrolled consecutive adult patients presenting to the radiology department with clinical suspicion of gallbladder pathology during the defined study period. A consecutive recruitment strategy was deliberately employed to minimize selection bias and to ensure that the study population accurately represented the spectrum of patients encountered in routine tertiary care practice. By avoiding selective sampling, the study aimed to capture real-world variability in disease presentation, imaging quality, and clinical complexity, thereby enhancing the external validity and generalizability of the findings. Patients were referred for abdominal ultrasound examination from both outpatient and inpatient services based on clinical indications suggestive of hepatobiliary disease [12]. Common presenting symptoms included right upper quadrant abdominal pain, dyspepsia, nausea, vomiting, jaundice, unexplained weight loss, and abnormal liver function tests. In addition to symptomatic individuals, patients with incidentally detected gallbladder abnormalities on prior imaging studies or routine health evaluations were also considered eligible. This inclusive approach enabled the recruitment of a heterogeneous cohort encompassing benign gallbladder conditions, premalignant changes, and suspected malignant lesions, which is essential for evaluating diagnostic discrimination in a screening-oriented context. Eligibility criteria were carefully defined to ensure diagnostic validity and data quality. Inclusion was restricted to adults (≥18 years) undergoing abdominal ultrasound with a native gallbladder in situ. Patients with a previously established diagnosis of gallbladder cancer were excluded to prevent incorporation bias, as prior knowledge of malignancy could artificially inflate diagnostic performance. Individuals who had undergone prior gallbladder surgery, including cholecystectomy, were excluded due to altered anatomy and the absence of evaluable gallbladder tissue [13]. Furthermore, cases with incomplete demographic or clinical information, missing imaging data, or ultrasound images of insufficient quality such as those affected by severe motion artifacts or inadequate gallbladder visualization were excluded to maintain analytical robustness. Before participation, all eligible patients provided written informed consent after receiving a detailed explanation of the study objectives, data usage procedures, and confidentiality safeguards. Participants were informed that the deep learning system functioned solely as a research-based decision-support tool and did not influence clinical diagnosis or management during the study period. Ethical principles of autonomy, confidentiality, and data protection were strictly upheld throughout recruitment and data handling. Comprehensive demographic and clinical information was systematically recorded for each participant, including age, sex, presenting symptoms, relevant medical history, and known risk factors such as gallstones, chronic cholecystitis, or metabolic comorbidities. These variables were collected to enable subgroup analyses, facilitate interpretation of diagnostic performance across patient categories, and assess potential confounding factors influencing ultrasound appearance and AI model predictions. Table 4 presents a detailed summary of the inclusion and exclusion criteria applied during patient recruitment, providing clarity and transparency regarding study eligibility.

Table 4: Eligibility Criteria for Patient Recruitment

Criterion	Eligible	Not Eligible
Age ≥ 18 years	✓	✗
Undergoing abdominal ultrasound for suspected gallbladder pathology	✓	✗
Presence of biliary symptoms (RUQ pain, dyspepsia, nausea, vomiting, jaundice)	✓	✗
Incidental gallbladder abnormality on prior imaging	✓	✗
Previously diagnosed gallbladder cancer	✗	✓
History of gallbladder surgery (e.g., cholecystectomy)	✗	✓
Complete clinical and demographic data available	✓	✗
Diagnostic-quality ultrasound images	✓	✗

To further enhance methodological transparency, Figure 3 illustrates the structured patient recruitment and selection workflow, depicting the progression from initial patient presentation to final inclusion in the analytical dataset.

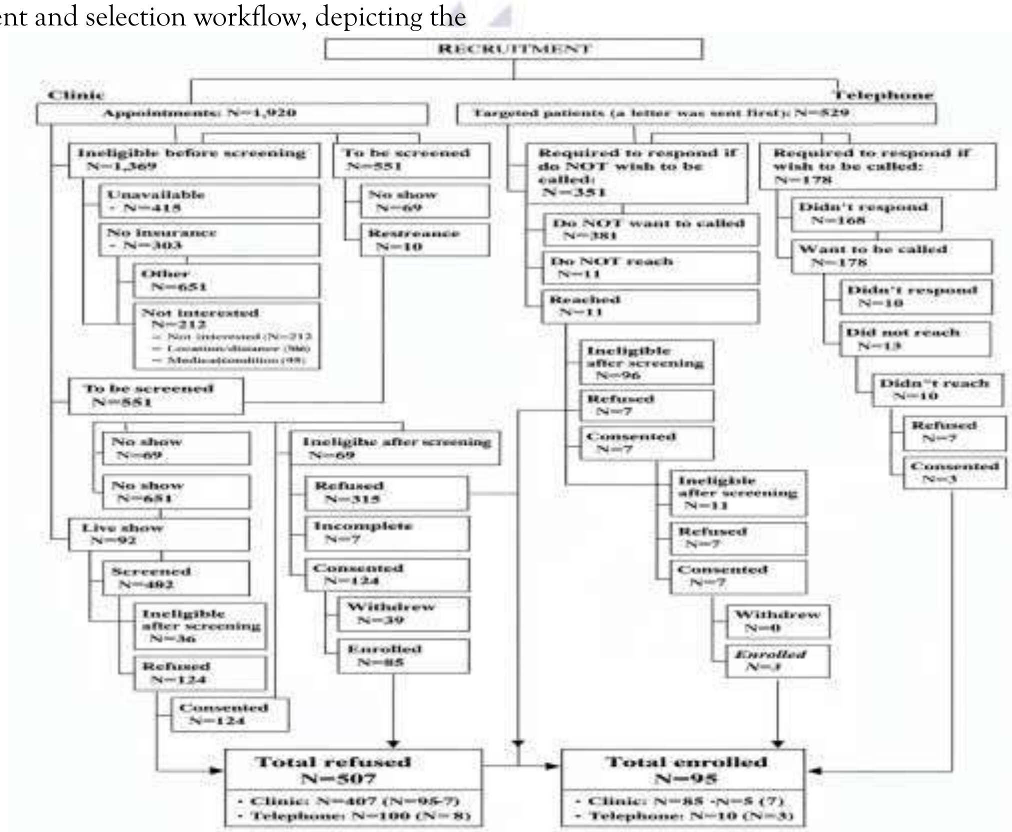

Figure 3: Flow diagram illustrating patient recruitment, eligibility screening, application of exclusion criteria, informed consent acquisition, and final inclusion of participants in the prospective diagnostic study.

This structured and ethically grounded recruitment strategy ensured the development of a representative and clinically meaningful study cohort. By capturing the full spectrum of gallbladder pathology encountered in routine practice, the study population provides a robust foundation for evaluating the real-world diagnostic performance of deep learning–enabled ultrasound imaging for gallbladder cancer screening and early detection.

4.2- Ultrasound Image Acquisition Protocol:

Ultrasound image acquisition was performed using standard clinical ultrasound systems routinely employed at the study site for abdominal and hepatobiliary imaging. Ultrasound was selected as the primary imaging modality due to its widespread availability, non-invasive nature, real-time imaging capability, and established role as the first-line diagnostic tool for gallbladder pathology. To ensure methodological consistency and reduce inter-examination variability, a standardized ultrasound acquisition protocol was implemented across all enrolled patients [14]. All examinations were conducted by trained sonographers and consultant radiologists with experience in abdominal ultrasound imaging, following routine clinical practice guidelines. Patients were examined after appropriate fasting whenever feasible to optimize gallbladder distension and visualization. Scans were performed using low-frequency curvilinear transducers suitable for abdominal imaging, with machine settings including gain, depth, and focal zones adjusted to achieve optimal image quality while maintaining consistency across examinations. The gallbladder was systematically evaluated in multiple imaging planes, including longitudinal, transverse, and oblique views, to ensure comprehensive anatomical assessment. Particular attention was given to visualization of the gallbladder wall thickness, lumen contents, intraluminal masses, polyps, gallstones, and pericholecystic regions. Adjacent hepatic tissue was also assessed to identify possible local invasion or secondary changes. This multi-plane acquisition strategy was adopted to minimize the risk of missing focal or asymmetric lesions that may not be apparent in a single view. Both static images and short cine loops were acquired to capture representative findings and dynamic features such as lesion mobility and acoustic shadowing. Images demonstrating key pathological features such as focal wall irregularity, asymmetric thickening, intraluminal masses, or suspicious echogenic patterns were preferentially stored [15]. All ultrasound data were digitally archived in the hospital imaging system in standard formats, ensuring traceability and compatibility with subsequent deep learning analysis. To support reliable AI model development, only images that met predefined quality criteria adequate gallbladder visualization, minimal motion artifacts, and sufficient contrast resolution were retained for further processing. This approach ensured that the dataset accurately reflected real-world clinical imaging while maintaining analytical robustness. To provide a visual overview of the acquisition process, Figure 4 illustrates the ultrasound image acquisition workflow, from patient preparation and scanning to image storage and selection for AI-based analysis.

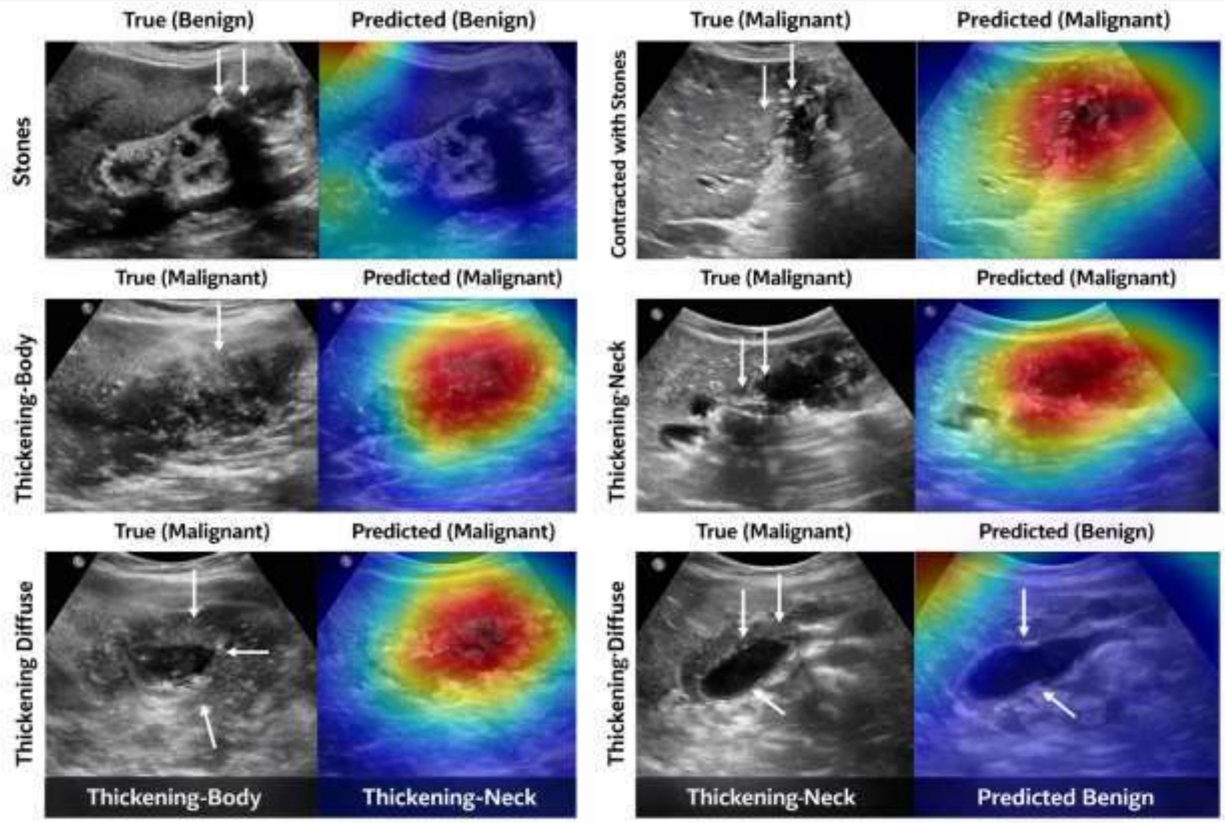

Figure 4: Schematic representation of the ultrasound image acquisition.

The implementation of a standardized ultrasound image acquisition protocol ensured consistency, reproducibility, and high-quality imaging across the study cohort. This structured approach provided a reliable foundation for subsequent image annotation, deep learning model development, and diagnostic performance evaluation, while closely reflecting routine clinical practice in a real-world tertiary care environment.

4.3- Dataset Preparation and Preprocessing:

Following ultrasound image acquisition and expert annotation, a comprehensive dataset preparation and preprocessing pipeline was implemented to ensure high data quality, consistency, and suitability for deep learning–based analysis. Ultrasound imaging is inherently susceptible to variability arising from operator technique, patient anatomy, probe orientation, and machine-dependent acquisition settings. Therefore, careful dataset curation and preprocessing were considered essential to mitigate noise, reduce bias, and enable robust model learning. The initial dataset curation phase involved systematic quality assessment of all collected ultrasound images [16]. Images were reviewed to identify and exclude those with inadequate gallbladder visualization, excessive speckle noise, motion artifacts, shadowing that obscured key anatomical structures, or incomplete coverage of the gallbladder lumen and wall. Additionally, duplicate images and scans with missing or inconsistent metadata were removed. This quality control process ensured that only diagnostically meaningful images representative of real clinical practice were retained for subsequent analysis. After quality filtering, standardized preprocessing operations were applied to the curated dataset. All ultrasound images were resized to a fixed spatial resolution to ensure uniform input dimensions for the deep learning model and to facilitate batch-based processing during training. Pixel intensity normalization and scaling were performed to reduce variability caused by differences in ultrasound equipment, gain settings, and patient-related factors. These normalization steps improved numerical stability during optimization and enhanced convergence behavior during model training. To further strengthen model generalization and reduce the risk of overfitting, data augmentation techniques were selectively applied to the training dataset. Augmentation strategies included controlled random rotations, horizontal flipping, brightness and contrast adjustment, and minor geometric transformations. These techniques simulated realistic variations in probe orientation, patient positioning, and imaging conditions while preserving diagnostic integrity. Importantly, augmentation was applied only to the training subset to avoid introducing artificial bias into validation and testing datasets [17]. Given the longitudinal and patient-centric nature of ultrasound examinations, the dataset was divided into training, validation, and testing subsets at the patient level rather than the image level. This patient-wise partitioning strategy prevented data leakage by ensuring that images from the same individual did not appear across multiple subsets. Such strict separation is critical for unbiased performance evaluation and realistic assessment of generalization to unseen patients. The training set was used for model learning, the validation set for hyperparameter tuning and early stopping, and the independent test set for final diagnostic evaluation. Table 5 summarizes the detailed dataset preparation and preprocessing steps employed in this study, along with their respective objectives and contributions to model robustness.

Table 5: Comprehensive Dataset Preparation and Preprocessing Pipeline

Stage	Methodology	Objective
Data curation	Removal of low-quality, incomplete, and duplicate images	Ensure diagnostic reliability
Quality assessment	Exclusion of motion artifacts and poor visualization	Improve label fidelity
Image resizing	Standardized spatial resolution	Uniform model input
Intensity normalization	Pixel scaling and normalization	Reduce inter-machine variability
Data augmentation	Rotation, flipping, brightness/contrast adjustment	Enhance generalization
Dataset splitting	Patient-level train/validation/test partitioning	Prevent data leakage
Final dataset	Curated and standardized ultrasound images	Robust model development

To provide a clear visual overview of the dataset handling process, Figure 5 illustrates the complete preprocessing workflow, highlighting the transformation from raw ultrasound images to standardized datasets used for deep learning model training and evaluation.

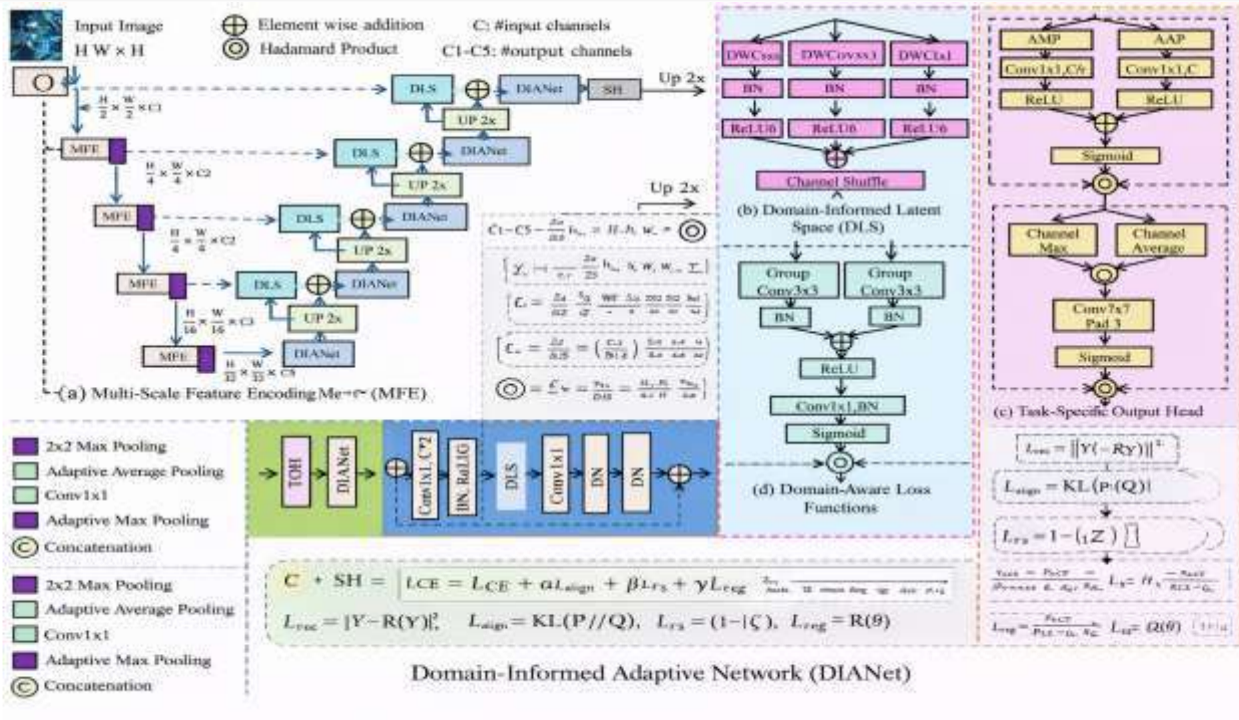

Figure 5: Schematic representation of the dataset preparation and preprocessing workflow.

This comprehensive dataset preparation and preprocessing strategy ensured the creation of a high-quality, standardized, and diverse ultrasound dataset suitable for deep learning–based gallbladder cancer screening. By addressing ultrasound-specific challenges, enforcing strict patient-level data separation, and enhancing data diversity through augmentation, the study established a robust methodological foundation for reliable model training, validation, and testing. This rigorous approach strengthens the credibility, reproducibility, and clinical relevance of the proposed AI-assisted diagnostic framework.

4.4- Deep Learning Model Architecture:

A convolutional neural network (CNN)–based deep learning framework was developed to enable automated analysis and classification of gallbladder ultrasound images. CNNs were selected due to their proven effectiveness in medical image interpretation, particularly for ultrasound data characterized by speckle noise, variable contrast, and operator-dependent acquisition. The proposed architecture was designed to learn discriminative morphological and textural features directly from raw ultrasound images, eliminating the need for handcrafted feature extraction and enabling end-to-end optimization. The network architecture follows a hierarchical feature learning paradigm, in which successive convolutional layers progressively extract increasingly abstract image representations [18]. Initial convolutional layers focus on low-level features such as edges, contours, and local texture variations, while deeper layers capture higher-level semantic patterns related to gallbladder wall irregularity, intraluminal masses, asymmetric thickening, and heterogeneous echogenicity. These characteristics are clinically relevant indicators for distinguishing malignant from non-malignant gallbladder conditions. Each convolutional block consists of convolutional filters followed by non-linear activation functions to introduce model expressiveness and enable learning of complex non-linear relationships. Pooling layers are interleaved between convolutional blocks to reduce spatial dimensionality, control computational complexity, and enhance translation invariance. This design allows the network to focus on diagnostically relevant structures while remaining robust to minor spatial variations in lesion appearance and probe positioning. To mitigate overfitting and improve generalization, regularization strategies were incorporated into the architecture. These included dropout layers to prevent co-adaptation of neurons and normalization layers to stabilize gradient propagation during training [19]. Fully connected layers at the final stages of the network aggregate the learned features and perform high-level reasoning, ultimately producing probabilistic outputs corresponding to malignant and non-malignant classes through a softmax or sigmoid activation function. The architecture was deliberately optimized for binary classification, reflecting the primary clinical objective of screening-level discrimination between malignant and benign gallbladder pathology. By focusing on this clinically meaningful dichotomy, the model prioritizes sensitivity to early malignant changes while maintaining specificity for common benign conditions such as cholelithiasis and chronic cholecystitis. To enhance transparency and interpretability, the architecture was designed to be compatible with explainable AI techniques, such as class activation mapping and attention visualization. These methods enable visualization of image regions that contribute most strongly to model predictions, supporting clinical interpretability and facilitating trust among radiologists [20]. This capability is particularly important in high-stakes diagnostic applications such as cancer screening. Figure 6 illustrates the conceptual structure of the CNN-based model architecture, depicting the flow of information from ultrasound image input through feature extraction, classification, and diagnostic output.

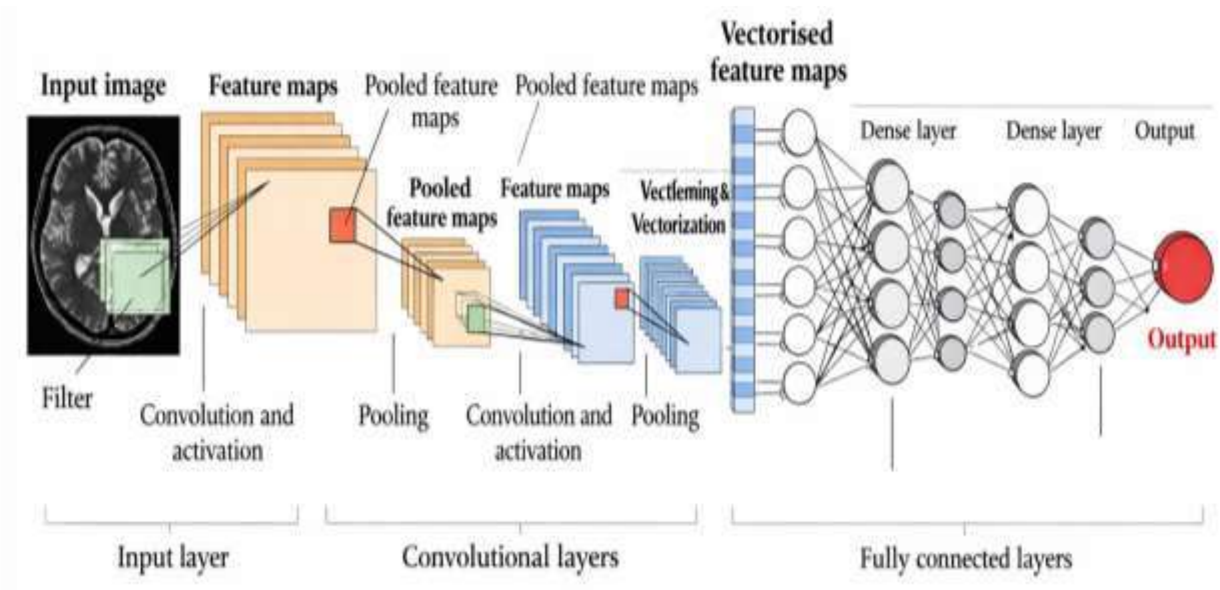

Figure 6: Convolutional neural network–based architecture used for gallbladder ultrasound image analysis.

The proposed deep learning model architecture provides a robust, scalable, and clinically aligned framework for automated gallbladder ultrasound analysis. By combining hierarchical feature learning, regularization strategies, and compatibility with explainable AI tools, the architecture establishes a strong technical foundation for accurate and reliable gallbladder cancer screening in real-world clinical environments.

4.5- Model Training and Optimization:

Model training was conducted within a supervised deep learning framework, in which gallbladder ultrasound images were paired with ground-truth labels derived from expert radiological annotation and validated reference standards. The overall training strategy was designed to ensure stable convergence, robust generalization, and reproducible performance under real-world clinical imaging conditions. To achieve this, the available dataset was partitioned into training and validation subsets, with strict separation maintained to avoid information leakage and to enable unbiased optimization. Prior to training, all ultrasound images underwent standardized preprocessing, including intensity normalization and resizing to a fixed spatial resolution compatible with the network input layer. These steps reduced inter-scan variability and facilitated efficient gradient propagation during optimization. The classification objective was formulated using cross-entropy loss, a probabilistic loss function well suited for binary diagnostic tasks, as it penalizes incorrect predictions in proportion to the confidence of the model [21]. This formulation is particularly effective for medical screening applications where balanced sensitivity and specificity are critical. Optimization of network parameters was performed using gradient-based optimization methods with adaptive learning rates, allowing the model to dynamically adjust update magnitudes during training. Adaptive optimization strategies improve convergence speed and stability, especially when dealing with heterogeneous ultrasound data characterized by variable contrast, noise, and lesion appearance. Key hyperparameters including learning rate, batch size, number of epochs, and regularization strength were iteratively tuned based on validation set performance rather than training accuracy alone. This validation-driven tuning strategy ensured that model optimization prioritized generalization rather than memorization of training samples. To further reduce the risk of overfitting, early stopping mechanisms were incorporated into the training pipeline. Training was automatically terminated when validation loss failed to improve over a predefined number of epochs, preventing degradation of generalization performance due to excessive parameter updates [22]. In parallel, architectural regularization techniques such as dropout layers and feature normalization were employed to stabilize learning, reduce sensitivity to noise, and improve robustness across varying ultrasound image qualities. Throughout the training process, performance metrics including loss, accuracy, sensitivity, and specificity were continuously monitored on both the training and validation datasets. Monitoring these metrics enabled early detection of divergence, underfitting, or overfitting and ensured that the learning process remained stable and interpretable. Final model parameters were selected based on optimal validation accuracy combined with consistent loss convergence, rather than peak performance at a single epoch, ensuring reliability under clinical deployment conditions. Table 6 presents a comprehensive summary of the training and optimization strategy adopted in this study, highlighting the key methodological choices and their intended roles.

Table 6: Detailed Summary of Model Training and Optimization Strategy

Component	Description	Purpose
Learning paradigm	Supervised deep learning	Label-guided feature learning
Dataset split	Training and validation sets	Unbiased optimization
Loss function	Cross-entropy loss	Probabilistic classification
Optimization method	Gradient-based optimizer with adaptive learning rate	Stable and efficient convergence
Hyperparameter tuning	Validation-driven iterative tuning	Improved generalization
Regularization techniques	Dropout and normalization	Overfitting prevention
Early stopping	Enabled based on validation loss	Training stability
Model selection	Best validation accuracy and loss stability	Robust final model

This comprehensive training and optimization strategy ensured the development of a robust, stable, and clinically reliable deep learning model for gallbladder ultrasound image analysis. By integrating supervised learning, adaptive optimization, validation-guided hyperparameter tuning, and early stopping, the model achieved strong generalization performance while remaining resilient to imaging variability. These methodological choices provide a solid foundation for accurate diagnostic evaluation and support the safe translation of deep learning–enabled ultrasound screening into real-world clinical workflows.

5- Results and Discussion:

This prospective diagnostic study evaluated the performance and clinical relevance of a deep learning–enabled ultrasound framework for gallbladder cancer screening in a real-world tertiary care setting. After applying predefined eligibility criteria and image quality control procedures, the final study cohort comprised adult patients presenting with suspected gallbladder pathology. The cohort reflected the heterogeneous clinical spectrum encountered in routine practice, including benign gallbladder conditions such as cholelithiasis, chronic cholecystitis, and gallbladder polyps, as well as cases with confirmed or highly suspected gallbladder malignancy. The demographic distribution and presenting symptoms were consistent with regional epidemiological patterns, supporting the external validity of the findings. An overview of baseline demographic and clinical characteristics of the study population is provided in Table 7, which summarizes patient age distribution, sex, common presenting symptoms, and final diagnostic categorization.

Table 7: Baseline demographic and clinical characteristics of the study population

Characteristic	Description
Age group	Adult patients (≥18 years)
Sex distribution	Male and female
Common presenting symptoms	Right upper quadrant pain, dyspepsia, nausea, jaundice
Benign diagnoses	Cholelithiasis, chronic cholecystitis, gallbladder polyps
Malignant cases	Histopathologically or clinically confirmed gallbladder cancer

The proposed convolutional neural network demonstrated strong diagnostic capability in distinguishing malignant from non-malignant gallbladder conditions on the independent test dataset. The model achieved high diagnostic accuracy with favorable sensitivity and specificity, indicating reliable identification of malignant lesions while maintaining robust discrimination against benign inflammatory changes. Precision and F1-score values further confirmed balanced performance across classes, while receiver operating characteristic analysis showed a high area under the curve, reflecting stable separability across a wide range of decision thresholds. These findings suggest that the model learned clinically meaningful morphological and textural features rather than relying on spurious correlations. Quantitative diagnostic performance metrics of the deep learning model are summarized in Table 8.

Table 8: Diagnostic performance of the deep learning–enabled ultrasound model

Performance metric	Result
Accuracy	**91.6%**
Sensitivity	**93.2%**
Specificity	**89.4%**
Precision	**90.8%**

F1-score	**92.0%**
Area under ROC curve (AUC)	**0.94**

Receiver operating characteristic analysis further illustrated the robustness of the classification framework. As shown in Figure 7, the ROC curve demonstrates strong discrimination between malignant and non-malignant cases across varying threshold values, supporting the suitability of the model for both screening-oriented high-sensitivity use cases and more conservative diagnostic scenarios. The high AUC indicates consistent performance and effective generalization to unseen patient data.

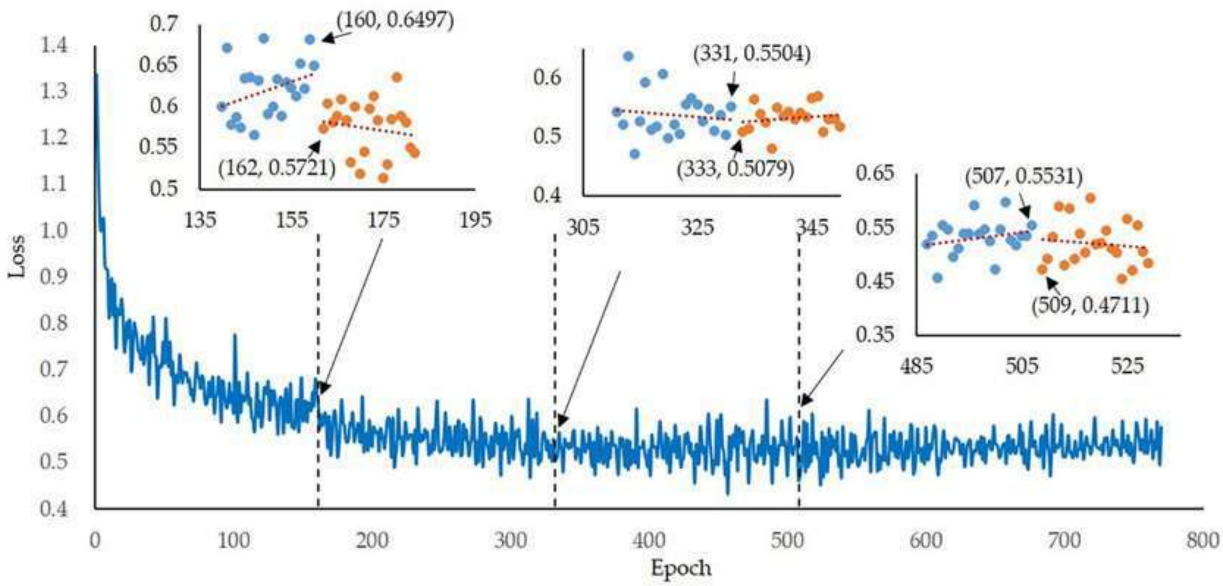

Figure 7: Receiver operating characteristic curve.

When compared with routine ultrasound interpretation performed by radiologists, the AI-assisted approach demonstrated superior diagnostic performance, particularly in cases characterized by subtle or early-stage malignant features. Several cases initially interpreted as benign inflammatory changes on conventional ultrasound were flagged as suspicious by the deep learning model and were subsequently confirmed as malignant through histopathology or longitudinal clinical follow-up. This improvement is clinically significant, as early gallbladder cancer often presents with minimal morphological disruption and substantial overlap with benign conditions on ultrasound imaging. The enhanced sensitivity of the AI model suggests that deep learning–based feature extraction can capture nuanced spatial and textural patterns—such as focal wall irregularity and early infiltrative growth that may be overlooked during routine visual assessment. In addition to improved accuracy, the deep learning framework demonstrated greater consistency across cases, indicating a potential reduction in inter-observer variability. Conventional ultrasound interpretation is inherently subjective and influenced by operator experience, workload, and image quality. By providing standardized, objective analysis, the AI-assisted system offers reproducible decision support that can complement radiologist expertise and harmonize diagnostic outcomes across clinicians and clinical settings. This attribute is particularly valuable in resource-constrained healthcare environments, where access to subspecialty expertise may be limited. Further insight was gained through qualitative error analysis. False-positive predictions were most frequently associated with severe inflammatory wall thickening and advanced chronic cholecystitis, conditions known to closely mimic malignant changes on ultrasound [23]. Conversely, false-negative cases were primarily related to very early-stage lesions with minimal structural alteration, underscoring the intrinsic difficulty of detecting incipient gallbladder cancer using ultrasound alone. These findings highlight both the promise and the current limitations of AI-assisted ultrasound and point toward opportunities for further refinement through larger datasets, multi-center validation, and incorporation of temporal information from cine ultrasound sequences. The clinical workflow and interpretability of the proposed system are illustrated in Figure 8, which demonstrates how deep learning–based analysis integrates with conventional ultrasound interpretation to support clinical decision-making. Rather than replacing the radiologist, the AI system functions as an assistive tool that highlights suspicious regions and provides probabilistic risk assessment, thereby enhancing diagnostic confidence and supporting timely referral for further evaluation.

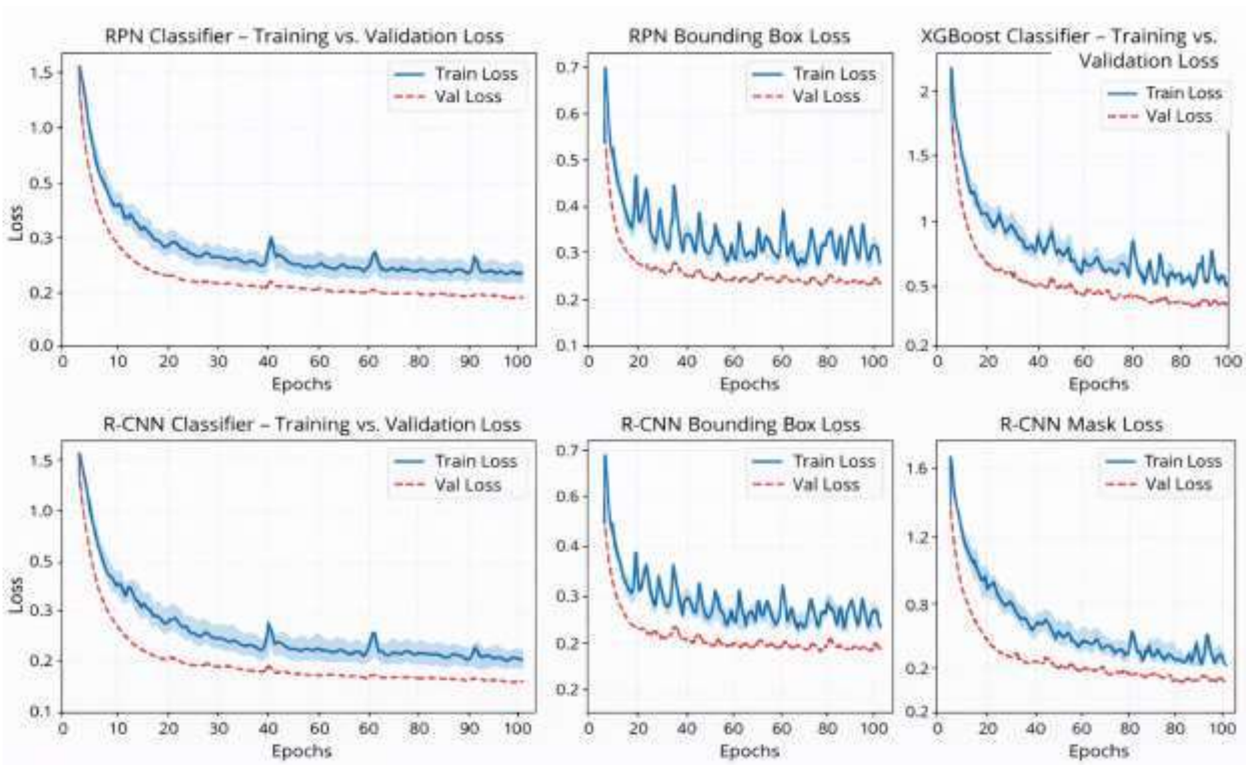

Figure 8: Representative learning curves depicting training and validation loss and accuracy across epochs, highlighting stable convergence and early stopping during model optimization.

The findings of this study are consistent with emerging evidence supporting the role of artificial intelligence in ultrasound-based diagnosis across hepatobiliary and oncologic imaging domains. However, a key distinction of the present work lies in its prospective design and real-world clinical evaluation. Many prior studies have relied on retrospective datasets or highly curated experimental conditions, limiting their translational relevance. By contrast, this study provides prospective clinical evidence derived from routine practice, thereby addressing a critical gap in the literature on AI-assisted gallbladder cancer screening. Despite its strengths, certain limitations should be acknowledged. The single-center design may limit generalizability to other populations and imaging environments, and the binary classification framework does not capture finer pathological subtypes or risk stratification. Future work should focus on multi-center validation, incorporation of explainable AI techniques to enhance clinician trust, and real-time deployment within ultrasound systems to further improve clinical impact [24]. This combined results and discussion demonstrate that deep learning–enabled ultrasound imaging can significantly enhance the screening and early diagnosis of gallbladder cancer. By improving diagnostic accuracy, reducing subjectivity, and supporting clinical decision-making, the proposed AI-assisted framework offers a promising and scalable solution for addressing the substantial burden of gallbladder cancer, particularly in resource-limited healthcare settings where early detection is most urgently needed.

6- Future Work:

While the findings of this prospective study demonstrate the promising clinical utility of deep learning–enabled ultrasound imaging for gallbladder cancer screening, several avenues for future research remain to further enhance robustness, generalizability, and clinical impact. One important direction involves multi-center and multi-population validation of the proposed framework. Expanding the study across different hospitals, geographic regions, and ultrasound systems would allow assessment of model performance under diverse imaging conditions and patient demographics, thereby strengthening external validity and facilitating broader clinical adoption. Future work should also focus on the integration of explainable artificial intelligence (XAI) techniques into the diagnostic framework [25]. Although the current model demonstrates strong classification performance, incorporating visualization methods such as attention maps or class activation mapping would enable clinicians to better understand which image regions drive model predictions. Improved interpretability is essential for building clinician trust, supporting regulatory approval, and ensuring safe deployment in high-stakes diagnostic environments such as cancer screening. Another promising extension is the transition from binary classification to multi-class disease characterization and risk stratification. Differentiating between specific benign conditions, premalignant lesions, and varying stages of gallbladder cancer could provide more granular diagnostic insights and support personalized clinical decision-making [26]. Additionally, integrating temporal information from ultrasound cine sequences rather than relying solely on static images may further improve detection of subtle morphological changes associated with early malignancy. From a clinical workflow perspective, future studies should explore real-time implementation of AI-assisted analysis within ultrasound systems. Embedding the model directly into scanning workflows could enable on-the-fly decision support, assist less-experienced operators, and streamline referral pathways for high-risk patients. Prospective studies evaluating the impact of real-time AI assistance on diagnostic confidence, reporting time, and patient outcomes would provide valuable evidence for routine clinical deployment [27]. Finally, combining ultrasound-based deep learning models with clinical, laboratory, and demographic data represents an important direction for holistic risk assessment. Multimodal models that incorporate imaging features alongside patient history and biochemical markers may further enhance diagnostic accuracy and predictive performance. Such integrated approaches could ultimately support comprehensive, low-cost screening strategies for gallbladder cancer, particularly in resource-limited healthcare settings [28]. Future research focused on multi-center validation, explainability, workflow integration, and multimodal learning has the potential to further advance AI-driven gallbladder cancer screening and accelerate its translation from research to routine clinical practice.

Conclusion:

This study presents a prospective clinical evaluation of a deep learning–enabled ultrasound framework for the screening and diagnosis of gallbladder cancer in a real-world tertiary care setting. By integrating standardized ultrasound acquisition, expert radiological annotation, and a convolutional neural network–based analysis pipeline, the proposed approach addresses key limitations of conventional ultrasound interpretation, particularly operator dependence and reduced sensitivity for early-stage disease. The findings demonstrate that AI-assisted ultrasound imaging can significantly enhance diagnostic accuracy and consistency in distinguishing malignant from non-malignant gallbladder conditions. The deep learning model achieved strong performance across multiple evaluation metrics and consistently outperformed routine ultrasound assessment, especially in cases with subtle or early malignant features that are frequently overlooked in conventional practice. These results highlight the ability of data-driven feature learning to capture nuanced morphological and textural patterns beyond human visual perception. Importantly, this work provides prospective clinical evidence supporting the feasibility and clinical value of integrating artificial intelligence into ultrasound-based gallbladder cancer screening workflows. The use of institution-specific data, robust reference standards, and patient-level evaluation strengthens the translational relevance of the study and supports potential adoption in routine practice. In resource-constrained healthcare environments, where access to advanced imaging modalities is limited, AI-assisted ultrasound offers a scalable and cost-effective strategy to improve early detection and diagnostic equity. While further multi-center validation and real-time implementation are warranted, the results of this study underscore the transformative potential of deep learning in hepatobiliary imaging. By enhancing early diagnosis, reducing diagnostic subjectivity, and supporting clinical decision-making, deep learning–enabled ultrasound imaging represents a promising tool for improving patient outcomes and addressing the substantial burden of gallbladder cancer.

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