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Tumor Discovery

ORIGINAL RESEARCH ARTICLE

Evaluating the effectiveness of artificial intelligence imaging in the qualitative diagnosis of pulmonary nodules

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Abstract

Our study aimed to evaluate the effectiveness of artificial intelligence (AI) image diagnostic systems in the qualitative diagnosis of pulmonary nodules. We analyzed 291 cases from June 2023 to January 2024 at Chongqing University Three Gorges Hospital. All patients in the study underwent low-dose chest computed tomography scans, which identified lung nodules, followed by thoracic surgery for pathological confirmation. We compared the predictive accuracy of AI-based diagnosis with that of physician-based diagnosis in distinguishing between benign and malignant lung nodules. Among the 291 lung nodules examined, 226 were cancerous, and 65 were benign. Receiver operating characteristic (ROC) curves, plotted based on the malignancy probabilities predicted by both methods, revealed that the AI group achieved an area under the ROC curve (AUC) of 0.727, with a sensitivity of 90.27% and a specificity of 58.46%. In comparison, the physician-reading group had an AUC of 0.737, with a sensitivity of 83.19% and a specificity of 66.15%. Our findings demonstrate that the AI diagnostic system effectively calculates malignancy probabilities for lung nodules, highlighting its significant predictive potential. This system can serve as a valuable adjunct tool for clinicians and imaging physicians in the diagnostic process.

Keywords: Artificial intelligence; Pulmonary nodule; Assisted diagnosis

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1. Introduction

Lung cancer exhibits the highest morbidity and mortality rates among malignancies worldwide, posing a significant threat to human health.[1] In 2022, China reported approximately 1,060,600 new cases of lung cancer and 733,300 deaths related to the disease, underscoring its substantial burden on public health. Despite recent advances in lung cancer treatment technology, about 75% of patients miss the optimal window for treatment due to delayed diagnosis.[2] Early diagnosis and appropriate treatment are essential for improving the survival rates of lung cancer patients, particularly through early detection.

Early lung cancer often manifests as isolated lung nodules, which can vary in characteristics and outcomes. A screening study in high-risk populations in Chinese communities revealed a 22.9% positive rate for lung nodules, with a malignancy rate of approximately 6.34% and a lung cancer detection rate of 1.5%.[3] According to the 2021 World Health Organization Classification of Thoracic Tumors,[4,5] carcinoma *in situ* and atypical adenomatous hyperplasia are considered precursor glandular lesions. A study[6] demonstrated that early diagnosis and complete resection of adenocarcinoma *in situ* and microinvasive adenocarcinoma resulted in 10-year disease-specific survival rates of 100%, with overall survival rates of 95.3% and 97.8%, respectively. However, the 5-year recurrence rate after complete resection of stage I invasive adenocarcinoma ranges from 10% to 30%.[7-9] For lung cancer presenting as solid nodules, delayed diagnosis and treatment significantly reduce 10-year survival, irrespective of the initial size and growth rate, particularly for rapidly growing nodules.[10] Therefore, early and effective identification of benign and malignant lung nodules is crucial in clinical practice. However, determining the nature of pulmonary nodules remains a major challenge and a focal point of ongoing research.

Low-dose computed tomography (LDCT) has proven highly effective in detecting early-stage lung cancer and has replaced chest X-rays as a more sensitive screening tool. Studies indicate that LDCT screening in high-risk groups significantly reduces the relative risk of lung cancer-related mortality.[11,12] Consequently, LDCT screening for high-risk populations is now recommended in China.[13,14] However, detecting lung nodules in computed tomography (CT) images remains challenging in routine clinical settings. First, lung nodules can be smaller than 3 mm, making them difficult for physicians to detect.[15] Second, physicians often focus primarily on the main clinical issue, potentially overlooking additional findings such as nodules.[16,17] Finally, the workload of physicians has dramatically increased over the past 15 years, largely due to the growing number of CT scans.[18] The increased risk of missed diagnoses for small nodules—driven by radiologists' fatigue and mental stress during mass screening of high-risk groups—underscores the need for more efficient nodule detection methods.

Artificial intelligence (AI) offers a promising solution to assist radiologists with these tasks. In recent years, AI has emerged as a significant tool across various medical fields, driving rapid advancements in precision medicine for cancer diagnosis and treatment.[19-23] The application of AI in medical imaging has also notably progressed, particularly in improving the detection rate of lung nodules. AI systems can analyze CT images using deep learning algorithms to efficiently identify small nodules in the early stages of lung cancer.[24] Research has demonstrated that AI systems, by learning from large volumes of cases, can automatically detect lung nodules, enhance sensitivity, and reduce the workload of radiologists.[25] These AI-assisted diagnostic systems have shown advantages in improving the visibility of lung nodules, assessing their malignant potential,[26] and accurately detecting nodules in complex lung diseases, thus providing reliable references for diagnosing primary lung cancer.[27]

In this study, we analyzed the pathological results of all lung nodules that met the inclusion criteria, compared detection outcomes between the AI-assisted group and the physician-reading group, and evaluated the accuracy of the AI system in predicting the malignancy probability of lung nodules. The aim of this evaluation is to assess the value of the AI system in the qualitative diagnosis of lung nodules.

2. Methods

2.1. Materials

All patients included in this study were admitted to Chongqing University Three Gorges Hospital between June 2023 and January 2024. Each patient underwent LDCT scans, which identified lung nodules. Following this, patients proceeded to thoracic surgery for pathological confirmation of the nodules.

Inclusion criteria:

(i) CT images displayed lung nodules with a maximum diameter of ≤30 mm, measured using the lung window.
(ii) Chest scans were reconstructed with a standard algorithm, featuring a layer thickness of 0.5 – 1.25 mm.
(iii) Patients had lung nodules with confirmed pathological results.
(iv) In cases with multiple lung nodules, only those with confirmed pathological results were included.

Exclusion criteria:

(i) Patients who had undergone invasive diagnostic or treatment procedures before the chest CT examination, such as puncture biopsy or radiofrequency ablation.
(ii) Patients who had received systemic chemotherapy, targeted therapy, or chest radiotherapy for tumors located in other parts of the body before the examination.
(iii) Patients with a history of other malignant tumors or metastatic cancer.
(iv) Patients who exhibited atelectasis, hilar lymph node enlargement, or pleural effusion.

A total of 291 patients met the inclusion criteria. This group consisted of 126 males and 165 females, aged

between 27 and 83 years, with a mean age of 57.07 years. The study encompassed 291 lung nodules, categorized into 65 benign nodules and 226 malignant nodules based on pathological findings. Among the malignant nodules, 215 were diagnosed as lung adenocarcinoma. This study was reviewed and approved by the ethics committee of our hospital (Ethics Approval Number 2023 Research No. [66]), and all enrolled patients provided informed consent.

2.2. Pathologic diagnostic methods

The results of the pathological examination were considered the gold standard in this study. All subjects underwent either trans-thoracic bronchoscopic puncture biopsy or lung nodule resection. We directed the obtained specimens to the pathology department for examination to determine the nature of the lung nodules and the pathological type of lung cancer. We recorded the results of these pathological examinations.

2.3. LDCT scanning methods

We followed the Chinese Lung Cancer Low-Dose Spiral CT Screening Guidelines (2018 edition) for image acquisition using a Philips 320-row and 640-slice CT scanner. The parameters for the LDCT scans included a tube voltage of 100 – 120 kV, a tube current of <70 mAs based on body mass index, a field of view of 500 mm, and a minimum layer thickness of 0.5 mm. We reconstructed the raw data into a thin layer with a thickness ranging from 0.5 – 1.25 mm.

2.4. Methods of reading images

We used both physician reading and an AI method to diagnose the CT images. The physician-reading group included two attending physicians with 10 years of experience in diagnosing chest images. They independently analyzed and diagnosed the lung nodules according to the "Chinese Expert Consensus on the Diagnosis and Treatment of Lung Nodules (2018 edition)." They classified lung nodules into six categories based on the Lung Imaging Reporting and Data System (Lung-RADS), as formulated by the American College of Radiology. In this study, we considered lung nodules categorized as two and three to be benign, while those categorized as four and above were considered malignant. We resolved any disagreements through discussion or consultation with a third investigator.

The AI reading group used the InferViewer v1.0.6 system for assisted diagnosis. We input images (DICOM format) of chest CT scans into the AI system, which then identified and calculated the average diameter, density classification, volume, and malignant probability of the lung nodules. The malignant probability ranged from 0 to 100%. The AI system indicated high-risk nodules (red) when the malignancy probability exceeded 70%, medium-risk nodules (yellow) when the probability was between 50% and 70%, and low-risk nodules (green) when the probability was below 50%. In this research, we categorized lung nodules as benign (malignant probability <70%) or malignant (malignant probability ≥70%) based on the malignant probability. Any AI diagnostic results that were questionable were reviewed by professional imaging physicians on the project team.

User Workflow (InferViewer v1.0.6 System): Doctors upload imaging data through the system interface, which then automatically performs lesion identification and analysis. Users can view the automatically generated lesion list, which includes various attributes and classifications of the nodules. The system provides a function to compare images from different time points, aiding doctors in assessing changes in the condition. Doctors can select different report templates to generate structured reports or use additional application tools for further analysis. They can also provide feedback on the system's predictions by marking missed nodules or removing false-positive lesions, which helps to enhance the system's accuracy and reliability.

AI Software Processing Workflow (InferViewer v1.0.6 System): The software employs AI, specifically deep learning, to automatically identify and analyze lung nodules in CT images. This includes automatic annotation, segmentation measurement, nature classification, and location pinpointing. The system features an intelligent follow-up option that monitors disease progression and provides re-examination suggestions by comparing a patient's medical imaging information over different periods. Based on this information, the system can generate structured image-text reports. Users can view the automatically generated lesion list, which includes various attributes (such as size and density, lobulation sign, spiculation sign, vascular convergence sign, air bronchogram sign, and pleural retraction sign) and classifications of nodules. The image workstation offers a variety of application tools, including length and angle measurements, to support comprehensive observation and multi-angle assessment of lesions by doctors.

2.5. Statistical analysis

We used SPSS 24.0 software exclusively for statistical analysis. Measurement data were expressed as mean ± standard deviation (x- ± s) if normally distributed, or as median (interquartile range) if not. Count data were reported as frequency and percentage, with qualitative data also expressed as percentages. We tested frequencies and percentages using the chi-square test, considering $P < 0.05$ as statistically significant. We used the Kappa consistency test to evaluate the agreement between the AI's

qualitative diagnosis of lung nodules and the pathological results, which served as the gold standard. To assess the diagnostic performance of both the AI and physician readings in identifying benign and malignant lung nodules, we employed the receiver operating characteristic (ROC) curve. Sensitivity and specificity were calculated based on the optimal cutoff value determined from the ROC analysis.

3. Results

3.1. Basic clinical information

We surgically removed and pathologically examined a total of 291 lung nodules. Of these, 65 were benign, and 226 were malignant. The nodules included 118 solid nodules, 102 partially solid nodules, and 71 pure ground-glass (nonsolid) nodules. The diameters of the nodules varied as follows: 0 – 10 mm in 59 cases, 11 – 20 mm in 149 cases, and 21 – 30 mm in 83 cases. We found no statistically significant differences between benign and malignant nodules regarding gender and nodule size ($P > 0.05$). However, the number of malignant nodules was significantly higher than that of benign nodules among both partially solid nodules ($P < 0.05$) and nonsolid nodules ($P < 0.05$). Furthermore, malignant nodules were significantly more prevalent in the lobes superior ($P < 0.05$) (Table 1).

3.2. Comparison of the efficacy of the AI diagnostic system and roentgenologist in identifying benign and malignant lung nodules

This study included a total of 291 lung nodules that met the criteria. All patients underwent thoracoscopic resection, which included wedge resection, segmentectomy, or lobectomy. We examined post-operative tissues using pathological methods. The results of the pathological examination served as the gold standard for this study. According to pathological diagnosis, benign nodules comprised inflammatory pseudotumor, hamartoma, organized pneumonia, tuberculosis, bronchogenic cyst, sclerosing pneumocytoma, and mycotic infection. Malignant nodules included adenocarcinoma, squamous carcinoma, poorly differentiated carcinoma, lymphoepithelioma-like carcinoma, neuroendocrine carcinoma, and small cell carcinoma. Inflammatory pseudotumors predominantly characterized benign nodules, while lung adenocarcinoma was the most common malignant nodule. We present the detailed statistics of pathological diagnoses in Table 2.

We compared AI-assisted diagnostic results with the pathological examination results. Among the 226 malignant lung nodules confirmed by pathology, AI correctly diagnosed 204 as malignant, misclassified 21 as benign, and failed to recognize one nodule (located near the hilum). Among the 65 benign lung nodules confirmed by pathology, AI accurately diagnosed 35 as benign, misclassified 27 as malignant, and failed to recognize three nodules (located near the hilum). The Kappa value for the agreement between AI diagnoses and pathological results was 0.4883 ($P < 0.001$), indicating moderate agreement. This result suggests that the qualitative diagnosis of lung nodules by AI generally aligns with pathological results (Table 3).

We analyzed the consistency between the diagnostic results from the physician-reading group and the pathological examination results. In the group of 226 malignant lung nodules confirmed by pathology, physicians diagnosed 188 as malignant, misclassified 11 as benign, and left 27 nodules unclassified. In the group of 65 benign lung nodules confirmed by pathology, physicians diagnosed 29 as benign, one as a calcified nodule, misclassified 22 as malignant, and left 13 nodules unclassified. The Kappa value for the agreement between physician diagnoses and pathological results was 0.5581 ($P < 0.001$), indicating moderate agreement. However, a significant number of nodules were left unclassified by the physicians (Table 4).

We plotted ROC curves based on the malignant probability of lung nodules predicted by the AI-assisted diagnostic system and the accuracy of physician readings. The area under the ROC curve (AUC) for the AI group was 0.727, with a sensitivity of 90.27% (95% confidence interval [CI]: 0.8563 – 0.9380) and a specificity of 58.46% (95% CI: 0.4556 – 0.7056). For the physician-reading

Table 1. Basic demographic and clinical information of subjects

Categorization	Sex		Average age	Nodule size (diameter, mm)			Nature of the nodule			Location of the nodule		
	Male	Female		0 – 10	11 – 20	21 – 30	Solid	Part-solid	Pure ground-glass	Lobus superior	Lobus middle	Lobus inferior
Benign lesions	28	37	57.61	17	34	14	47	10	8	27	9	29
Malignant lesions	98	128	59.86	42	115	69	71	92	63	145	24	57
P-value	1			0.2372			2.428e-08			0.003591		

group, the AUC was 0.737, with a sensitivity of 83.19% (95% CI: 0.7766 – 0.8782) and a specificity of 66.15% (95% CI: 0.5335 – 0.7743). Both the AI group and the physician-reading group demonstrated good predictive value for the qualitative diagnosis of lung nodules. The AI group exhibited higher sensitivity compared to the physician-reading group, while the physician group showed higher specificity than the AI group (Figure 1 and Table 5).

Table 2. Post-operative pathological test results of pulmonary nodules

Lesion type	Benign group (quantities)	Malignant group (quantities)
Inflammatory pseudotumor	39	-
Hamartoma	9	-
Organized pneumonia	8	-
Tuberculosis	5	-
Bronchogenic cyst	1	-
Sclerosing pneumocytoma	1	-
Mycotic infection	1	-
Benign lesion	1	-
Adenocarcinoma	-	215
Squamous carcinoma	-	5
Poorly-differentiated carcinoma	-	3
Lymphoepithelioma-like carcinoma	-	1
Neuroendocrine cancer	-	1
Small cell carcinoma	-	1
Total	65	226

4. Discussion

Primary bronchopulmonary cancer, commonly known as lung cancer, is a globally significant malignant tumor with high mortality rates.[28] In 2022, lung cancer was the most common malignancy in China, accounting for 18.06% of new cases and 23.9% of fatalities.[29] With projections indicating a 50% increase in cancer burden by 2040 compared to 2020, early screening and diagnosis are becoming increasingly crucial. Advances in precision medicine, such as targeted therapies and immunotherapies, have markedly improved outcomes and survival rates for lung cancer patients.[30] Nonetheless, early detection remains essential, as the prognosis of lung cancer heavily depends on the stage of the disease. For example, the 5-year survival rate for stage IA lung cancer can reach 85%, while it drops to only 6% for stage IV.[31] Early-stage lung cancer often lacks obvious symptoms, leading to most cases being diagnosed at advanced stages, where the 5-year survival rate falls below 20%.[32] Currently, imaging plays a critical role in the early screening and diagnosis of lung cancer, with early-stage lung cancer typically presenting as lung nodules on imaging. Accurate identification of the benign or malignant nature of these nodules through imaging features is crucial for clinicians and imaging physicians to provide timely and effective treatment for patients with malignant lung nodules.

Table 3. Consistency test results of the AI group

AI	Pathological findings		Total	Kappa value	*P*-value
	Malignant nodules	Benign nodules			
Malignant nodules	204	27	231	0.4883	1.529e-14
Benign nodules	21	35	56		
Unidentified	1	3	4		
Total	226	65	291		

Abbreviation: AI: Artificial intelligence.

Table 4. Consistency test results of the physician-reading group

Physicians-reading group	Pathological findings		Total	Kappa value	*P*-value
	Malignant nodules	Benign nodules			
Malignant nodules	188	22	210	0.5581	2.052e-16
Benign nodules	11	29	40		
Calcified nodule	0	1	1		
Uncategorized	27	13	40		
Total	226	65	291		

Analyzing a large volume of CT images presents a significant challenge, with the risk of missed diagnoses due to the fatigue and mental stress associated with mass screening of high-risk groups. Therefore, accurately identifying high-risk nodules within a vast number of images has become an urgent clinical need.

Numerous studies have shown that AI diagnostic systems can outperform imaging physicians in detecting lung nodules.[33-36] Using precise algorithmic models, we can rapidly detect lung nodules, perform qualitative analyses, and predict their benign or malignant nature. This reduces subjective bias and enhances the efficiency and objectivity of lung nodule analysis. Consequently, imaging physicians are partially relieved from the repetitive and time-consuming task of nodule detection, allowing them to focus more on determining the malignancy of nodules.

Research indicates that applying AI to CT image recognition significantly improves the efficiency of lung cancer screening and diagnosis.[26] Our project's results showed that the AI system achieved a sensitivity of 90.27% (95% CI: 0.8563 – 0.9380) in differentiating benign from malignant lung nodules, which exceeds the sensitivity of 83.19% (95% CI: 0.7766 – 0.8782) observed in physician readings. The AI diagnostic imaging system demonstrated strong sensitivity in the qualitative diagnosis of lung nodules, surpassing the physician-reading group. This result aligns with the 75.6% – 100% sensitivity range for AI reported in several studies.[33,37,38]

Table 5. Sensitivity and specificity analysis of the qualitative diagnoses of the pulmonary nodules in the AI group and the physician-reading group

Group	Area under curve	Sensitivity	Specificity
Physicians-reading group	0.737	0.8319	0.6615
AI group	0.727	0.9027	0.5846

Abbreviation: AI: Artificial intelligence.

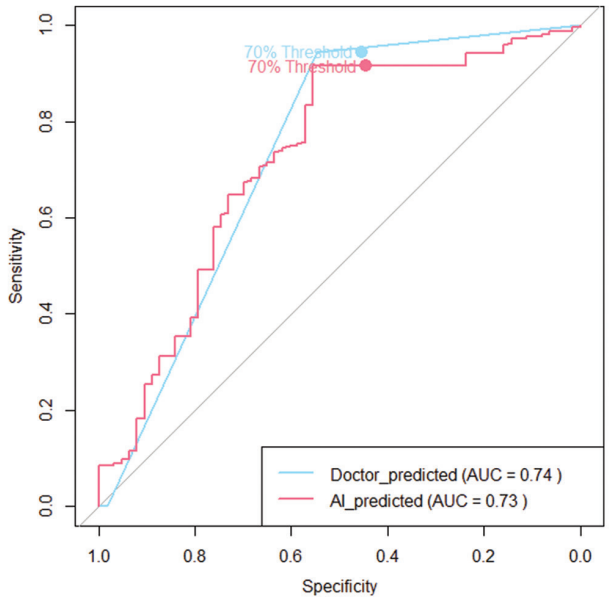


Figure 1. Receiver operating characteristic curves based on the qualitative diagnoses of the pulmonary nodules in the AI group and the physician-reading group
Abbreviations: AUC: Area under curve; AI: Artificial intelligence.

In the physician-reading group, nearly 40 pulmonary nodules were not assessed for risk or categorized as benign or malignant. This may be because radiologists subjectively deemed the nodules at risk for malignancy, despite the absence of typical malignant signs in the images. This situation challenges clinicians in determining the appropriate diagnosis and treatment plan for patients with nodules. During pulmonary nodule follow-up, dynamic changes in size or enlargement of the solid component can help clinicians more accurately assess nodule malignancy. However, many ground-glass nodules are small and grow slowly, leading to discrepancies among clinicians and radiologists in their assessments. This creates challenges in determining the optimal timing for intervention in patients. AI can access baseline LDCT data and provide follow-up LDCT evaluations, monitoring disease progression by comparing a patient's medical imaging information over different periods. By comparing and analyzing images of the same nodule at different times, the AI diagnostic imaging system assesses changes in size, volume, and density, offering greater stability and objectivity in assisting with clinical diagnosis and treatment (Figure 2).

Our findings revealed that the AI system exhibited a specificity of 58.46% (95% CI: 0.4556 – 0.7056) in differentiating benign from malignant lung nodules, which is lower than the specificity of 66.15% (95% CI: 0.5335 – 0.7743) observed in the physician-reading group. This discrepancy could be related to the tendency of AI systems to misdiagnose lung nodules as intrapulmonary lymph nodes due to interference from vascular and bronchial structures, leading to lower diagnostic specificity compared to imaging physicians.[19] In addition, AI primarily calculates the malignant risk of lung nodules based on factors such as size, density, lobulation sign, spiculation sign, vascular convergence sign, air bronchogram sign, and pleural retraction sign. However, some inflammatory nodules may also exhibit lobulation and spiculation on imaging, which increases the false positive rate for malignant nodules. Since AI cannot flexibly assess and comprehensively analyze a

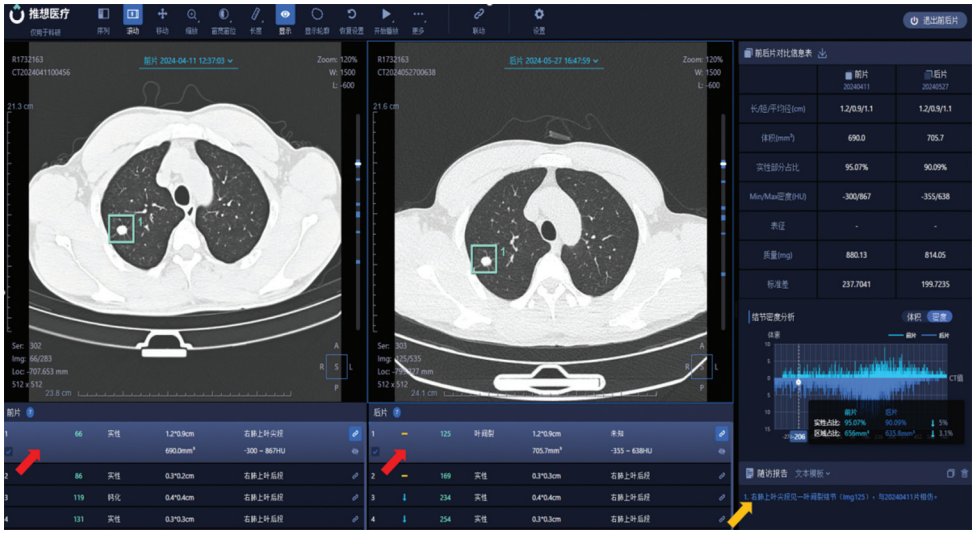


Figure 2. Artificial intelligence diagnostic systems (Infervision InferViewer v1.0.6 system) were used to compare the function of pulmonary nodules during different time periods. The green boxes show the same nodule at different time points. The red arrows suggest specific information about the images of the nodules, including their location, size, nature, density, and volume. Specific data comparisons are shown in the information table on the right. Yellow arrows show the conclusions drawn after the comparison.

patient's clinical data, the specificity in diagnosing benign versus malignant pulmonary nodules remains low. In contrast, clinicians in the physician-reading group can combine patient clinical data and test results to make a more comprehensive evaluation of pulmonary nodules, which can improve the specificity of the qualitative diagnosis.

AI diagnostic systems offer advantages in the accuracy and effectiveness of diagnosing lung nodules, but they still have certain limitations. First, AI imaging diagnosis has a high false-positive rate, requiring collaboration between engineering technicians and clinicians to optimize algorithms and reduce false positives while maintaining sensitivity. Second, in this study, the AI imaging group failed to identify four cases of nodules near the hilum, suggesting a reduced sensitivity to nodules in this region. This limitation may result from the pre-training model used to build the AI database, which primarily focused on small peripheral nodules, thereby limiting the diagnostic value of AI imaging for central-type lung cancer. Third, many patients undergoing treatment currently present with mixed-density ground-glass nodules, for which the diagnostic value of AI imaging surpasses that of solid nodules. Fourth, AI does not demonstrate a significant advantage over physician readings in the qualitative diagnosis of pulmonary nodules when using enhanced CT or non-thin layer CT scans. Previous research by Jianghong *et al.*[39] reviewed 88 cases of lung subsolid nodules, finding that the AI system based on CT plain scanning and CT enhancement achieved a detection sensitivity of 100%. However, AI did not significantly aid in judging the nature of lung subsolid nodules on enhanced CT. Similarly, Liu *et al.*[40] demonstrated that the AI detection rate is comparable to manual reading for 1-mm-thick chest CT scans, but AI is less specific than manual reading for 5-mm-thick chest CT scans. Therefore, when using AI systems, thin chest CT should be chosen to achieve optimal results.

As the adoption of AI continues to grow, the ongoing enhancement of AI image-assisted diagnosis is essential. This improvement requires close collaboration between clinicians and AI engineers, with clinicians clearly articulating their clinical needs and specific requirements. Given AI's self-learning capabilities, as clinical applications expand and the volume of examinations increases, AI-assisted diagnosis will continue to advance. At present, AI systems exhibit high accuracy in screening and diagnosing lung nodules, providing valuable auxiliary tools for clinicians and imaging physicians.

5. Conclusion

This study demonstrates that AI-assisted imaging can significantly aid in the qualitative diagnosis of pulmonary nodules, offering significant guidance for clinicians in the early diagnosis and management of these nodules. However, the AI-assisted diagnosis system must be further refined to address its current limitations. As AI technology evolves, future advancements may incorporate multiple factors, such as patients' family history, age, smoking history, and lung cancer biomarkers, to enhance the accuracy and specificity of lung nodule diagnosis.

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Conflict of interest

The authors declare that they have no competing interests.

Author contributions

Conceptualization: Chunlan Hu, Long Zhou
Formal analysis: All authors
Investigation: All authors
Methodology: All authors
Writing – original draft: Chunlan Hu
Writing – review & editing: Chunlan Hu, Long Zhou

Ethics approval and consent to participate

The Ethics Committee of our hospital reviewed and approved the study (Ethics Approval Number 2023 Research No. [66]), and all enrolled patients provided informed consent.

Consent for publication

All participants gave consent to publish their data in this study, and personal identifiers have been anonymized to ensure privacy.

Availability of data

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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