Radiology Open Access Journal

Case Report Open Access

Comparative Analysis of Lung-RADS 2022 and Chinese Expert Consensus 2024 for Pulmonary Nodule Management in East African Population: A Dual-Guideline Validation Study

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Received: 03 Jan 2026
Accepted: 13 Jan 2026
Published: 20 Jan 2026
J Short Name: ROAJ

Keywords:

Lung-RADS; Pulmonary Nodule; Diagnostic Accuracy; East Africa; Lung Cancer Screening; Chinese Guidelines; Artificial Intelligence

Citation:

Juan Zuo, Comparative Analysis of Lung-RADS 2022 and Chinese Expert Consensus 2024 for Pulmonary Nodule Management in East African Population: A Dual-Guideline Validation Study. Radiology Open Acc Jour 2026; V11(1): 1-9

1. Abstract

1.1. Background

Pulmonary nodule evaluation in resource-limited settings with high infectious disease burden remains challenging. This investigation assessed the diagnostic accuracy of Lung-RADS 2022 and Chinese Expert Consensus 2024 among patients screened at Abdulla Mzee hospitals on Pemba Island, Tanzania.

1.2. Methods

A retrospective analysis encompassed 683 pulmonary nodules confirmed by histopathology or minimum 24-month imaging surveillance. Sensitivity, specificity, positive and negative predictive values, along with Cohen's kappa coefficient, were computed for each classification framework, with pathological diagnosis serving as the reference standard.

1.3. Results

Malignant nodules comprised 110 cases (16.1%). Lung-RADS 2022 demonstrated sensitivity of 93.6% (95% CI: 87.4-96.9) and specificity of 90.1% (95% CI: 87.3-92.2). The Chinese Consensus achieved 91.8% sensitivity and 90.9% specificity. Both systems yielded negative predictive values exceeding 98%. Malignant lesions exhibited statistically larger dimensions compared to benign counterparts (11.4±5.9mm vs. 9.5±4.6mm, $P<0.001$).

1.4. Conclusions

Both classification systems maintained high diagnostic performance in this epidemiologically distinct population. These observations substantiate the applicability of established guidelines within African healthcare contexts characterized by substantial infectious disease prevalence.

2. Introduction

Lung cancer continues to impose substantial mortality globally, with over 2.2 million incident cases documented annually according to recent epidemiological estimates [1]. While low-dose computed tomography screening has demonstrated mortality reduction benefits within high-risk cohorts [2], the practical implementation of lung cancer screening programs across resource-constrained regions confronts numerous obstacles. The differential diagnosis of pulmonary nodules becomes particularly complex in geographical areas where infectious pulmonary conditions, including tuberculosis and various parasitic diseases, prevail.

The Lung Imaging Reporting and Data System, initially released by the American College of Radiology and subsequently revised in 2022, provides standardized nomenclature for pulmonary nodule classification based upon dimensional and morphological characteristics [3]. The most recent iteration introduced refined management recommendations for subsolid nodules alongside volumetric assessment parameters [4]. Conversely, the Chinese Expert Consensus on Pulmonary Nodule Management, updated in 2024, was specifically developed to accommodate the epidemiological profile observed in Asian populations, incorporating both radiological manifestations and clinical risk determinants [5].

Despite widespread implementation throughout Western and Asian healthcare systems, external validation data concerning the performance of these classification frameworks within sub-Saharan African populations remains conspicuously limited [6]. Pemba Island, situated within the United Republic of Tanzania, epitomizes a distinctive epidemiological environment characterized by elevated tuberculosis prevalence alongside constrained healthcare infrastructure [7]. This investigation was designed to systematically evaluate the diagnostic performance of Lung-RADS 2022 and the Chinese Expert Consensus 2024 within this historically underrepresented population, while concurrently examining the diagnostic capability of artificial intelligence-assisted interpretation.

3. Materials and Methods

3.1. Study Design and Population

This retrospective diagnostic accuracy study was conducted at Abdulla Mzee Hospital, Pemba Island, Zanzibar, Tanzania., spanning the period from January 2022 through June 2024. The institutional review board approved the study protocol (2025K021), and the requirement for individual informed consent was waived given the retrospective nature of the analysis.

Eligibility criteria encompassed the following parameters: individuals aged 18 years or older presenting with pulmonary nodules measuring at least 4mm in maximum diameter on computed tomography examination, availability of histopathological confirmation or completion of minimum 24-month imaging surveillance, and adequate computed tomography image quality permitting comprehensive analysis. Exclusion criteria comprised prior malignancy history, previous pulmonary surgical intervention or radiation therapy, incomplete clinical documentation, and inadequate follow-up imaging. Ultimately, 683 pulmonary nodules derived from 683 patients satisfied all inclusion requirements and were incorporated into the final analytical dataset.

3.2. CT Imaging Protocol

All computed tomography (CT) examinations were performed using a Siemens 64-slice spiral CT scanner (Somatom Definition AS+, Siemens Healthineers) with standardized acquisition parameters: tube potential 120 kVp, automated tube current modulation, reconstruction section thickness 1.0mm, and reconstruction interval 0.8mm. Image reconstruction incorporated both lung window (width 1500 HU, level -600 HU) and mediastinal window (width 350 HU, level 40 HU) display settings.

3.3. Image Analysis

Two board-certified radiologists, possessing 5 and 8 years of subspecialty experience in thoracic imaging respectively, independently evaluated all computed tomography examinations. Readers remained blinded to clinical information and histopathological outcomes. For each identified nodule, the following characteristics were systematically documented: maximum diameter (millimeters), anatomical location, margin characteristics, internal density, and presence of calcification or cavitation.

3.4. Application of Classification Systems

Nodule classification according to Lung-RADS 2022 employed the following categories: Category 1 (negative), Category 2 (benign), Category 3 (probably benign), Category 4A (moderately suspicious), Category 4B (highly suspicious), and Category 4X (additional concerning features) [3,4]. For analytical purposes, categories 4A, 4B, and 4X were collectively designated as positive indicators of malignancy.

Risk stratification according to Chinese Expert Consensus 2024 utilized a three-tier classification: Low risk (nodules smaller than 8mm without malignant features), Intermediate risk (nodules measuring 8-15mm or exhibiting some malignant features), and High risk (nodules exceeding 15mm or demonstrating definite malignant characteristics including spiculation, lobulation, or pleural retraction) [5]. High-risk classification was interpreted as malignancy positive.

3.5. AI-Assisted Diagnosis

A commercially available deep learning system for pulmonary nodule detection and characterization (Version 3.0, InferVision Medical Technology) was applied to all computed tomography examinations. The artificial intelligence algorithm generated malignancy probability scores ranging from 0 to 100%, with scores of 65% or higher classified as positive for malignancy based upon manufacturer-recommended threshold.

3.6. Reference Standard

Histopathological diagnosis obtained through computed tomography-guided percutaneous biopsy, bronchoscopic biopsy, or surgical resection constituted the reference standard. For nodules lacking histopathological confirmation, computed tomography stability persisting for at least 24 months served as acceptable evidence of benignity, consistent with established international recommendations [8,9].

3.7. Statistical Analysis

Statistical computations employed SPSS software (version 26.0, IBM Corporation) and R programming environment (version 4.1.2). Continuous variables were expressed as mean ± standard deviation, with group comparisons utilizing independent samples t-test or Mann-Whitney U test as appropriate. Categorical variables were presented as counts and percentages, compared through chi-square test or Fisher's exact test. Diagnostic perfor-

mance metrics including sensitivity, specificity, positive predictive value, negative predictive value, accuracy, and corresponding 95% confidence intervals were calculated. Cohen's kappa coefficient quantified agreement between each classification system and histopathological diagnosis. McNemar's test facilitated statistical comparison of diagnostic performance between the two classification frameworks. All hypothesis tests employed two-sided significance threshold of 0.05. This investigation adhered to the STARD 2015 guidelines for diagnostic accuracy study reporting [10].

4. Results

4.1. Baseline Characteristics

Among the 683 pulmonary nodules subjected to analysis, 110 (16.1%) were histopathologically confirmed as malignant while 573 (83.9%) were determined to be benign. The mean nodule diameter measured 9.8±4.9mm (range: 4-32mm). Patient demographic characteristics and nodule features are summarized in Table 1. The mean patient age was 57.6±13.0 years, with 360 (52.7%) males and 323 (47.3%) females. A smoking history was documented in 105 (15.4%) individuals in Table 1.

Table 1: Baseline Characteristics of Patients with Pulmonary Nodules Stratified by Malignancy Status.

Variable	Malignant (n=110)	Benign (n=573)	t-value or χ^2-value	P-value
Age (years, mean ± SD)	56.4 ± 12.9	57.8 ± 13.1	-0.980	0.327
Male gender, n (%)	59 (53.6)	301 (52.5)	0.012	0.914
Smoking history, n (%)	48 (43.6)	57 (9.9)	77.936	<0.001
Nodule size (mm, mean ± SD)	11.4 ± 5.9	9.5 ± 4.6	3.65	<0.001
CT manifestation score (mean ± SD)	7.3 ± 1.5	4.7 ± 1.6	15.710	<0.001

Note: CT = computed tomography; SD = standard deviation. Continuous variables were compared using independent samples t-test; categorical variables were compared using chi-square test. P-values < 0.05 were considered statistically significant.

4.2. Distribution of Nodule Classifications

Nodule classification distributions according to Lung-RADS 2022 and Chinese Consensus 2024 are illustrated in Figure 1. The Lung-RADS categorization revealed the following distribution in Table 2: Category 1 encompassed 194 nodules (28.4%), Category 2 comprised 205 cases (30.0%), Category 3 included 207 specimens (30.3%), Category 4A contained 50 nodules (7.3%), Category 4B accounted for 17 lesions (2.5%), and Category 4X comprised 10 instances (1.5%). Under Chinese Consensus 2024 classification, 317 nodules (46.4%) were categorized as low risk, 269 (39.4%) as intermediate risk, and 97 (14.2%) as high risk in Table 3.

Table 2: Distribution of Pulmonary Nodules According to Lung-RADS 2022 Classification.

Category	Total n (%)	Malignant n	Malignancy Rate (%)
Category 1 (Negative)	194 (28.4)	34	17.5
Category 2 (Benign)	205 (30.0)	35	17.1
Category 3 (Probably benign)	207 (30.3)	28	13.5
Category 4A (Suspicious)	50 (7.3)	12	24.0
Category 4B (Very suspicious)	17 (2.5)	1	5.9
Category 4X (Additional features)	10 (1.5)	0	0.0

Table 3: Distribution of Pulmonary Nodules According to Chinese Expert Consensus 2024.

Risk Level	Total n (%)	Malignant n	Malignancy Rate (%)
Low risk	317 (46.4)	46	14.5
Intermediate risk	269 (39.4)	50	18.6
High risk	97 (14.2)	14	14.4

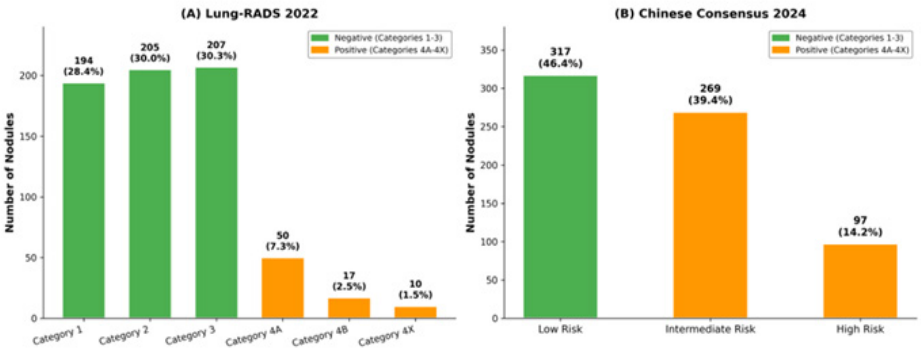

Figure 1: Distribution of pulmonary nodules according to Lung-RADS 2022 and Chinese Expert Consensus 2024 classification systems.

4.3. Diagnostic Performance

The diagnostic performance metrics for Lung-RADS 2022, Chinese Consensus 2024, and artificial intelligence-assisted interpretation are detailed in Table 4. Lung-RADS 2022 attained sensitivity of 93.6% (95% CI: 87.4-96.9%) and specificity of 90.1% (95% CI: 87.3-92.2%), AUC=0.918. Chinese Consensus 2024 demonstrated sensitivity of 91.8% alongside specificity of 90.9%, AUC=0.914. The artificial intelligence algorithm achieved sensitivity of 90.9% and specificity of 89.0%, AUC=0.900. Both classification systems produced negative predictive values exceeding 98%, indicating robust capability for malignancy exclusion.

Table 4: Diagnostic Performance Comparison of Lung-RADS 2022, Chinese Expert Consensus 2024, and AI-Assisted Diagnosis.

Index	Lung-RADS 2022	Chinese Consensus 2024	AI-assisted
Sensitivity (%)	93.6 (95% CI: 87.4-96.9)	91.8 (95% CI: 85.2-95.6)	90.9 (95% CI: 84.1-95.0)
Specificity (%)	90.1 (95% CI: 87.3-92.2)	90.9 (95% CI: 88.3-93.0)	89.0 (95% CI: 86.2-91.3)
PPV (%)	64.4	66.0	61.3
NPV (%)	98.7	98.3	98.1
Accuracy (%)	90.6	91.1	89.3
AUC	0.918	0.914	0.900
Kappa (95% CI)	0.707 (0.639-0.775)	0.715 (0.646-0.783)	0.669 (0.597-0.741)
True Positive	103	101	100
False Positive	57	52	63
True Negative	516	521	510
False Negative	7	9	10

Note: CI = confidence interval; PPV = positive predictive value; NPV = negative predictive value. 95% CIs for sensitivity and specificity were calculated using Wilson score interval. Lung-RADS 2022 Categories 4A, 4B, and 4X were classified as positive for malignancy; Chinese Consensus 2024 high-risk classification was interpreted as malignancy positive; AI malignancy probability threshold was ≥65%.

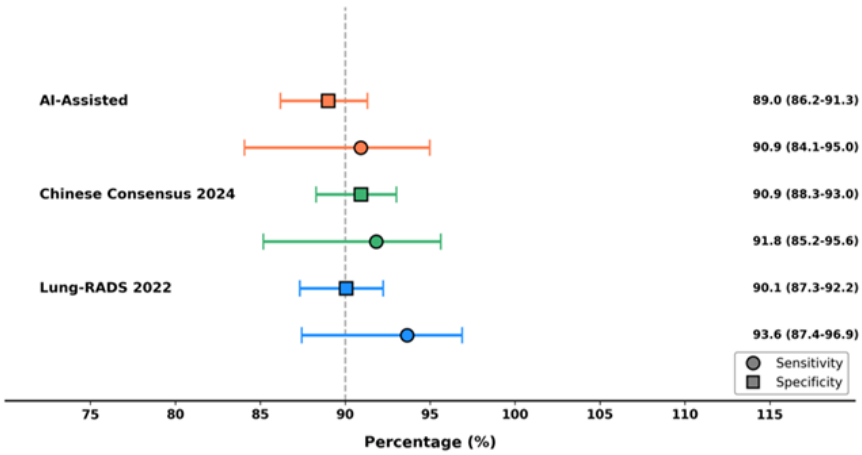

Figure 2: Forest plot displaying sensitivity and specificity with 95% confidence intervals for each diagnostic.

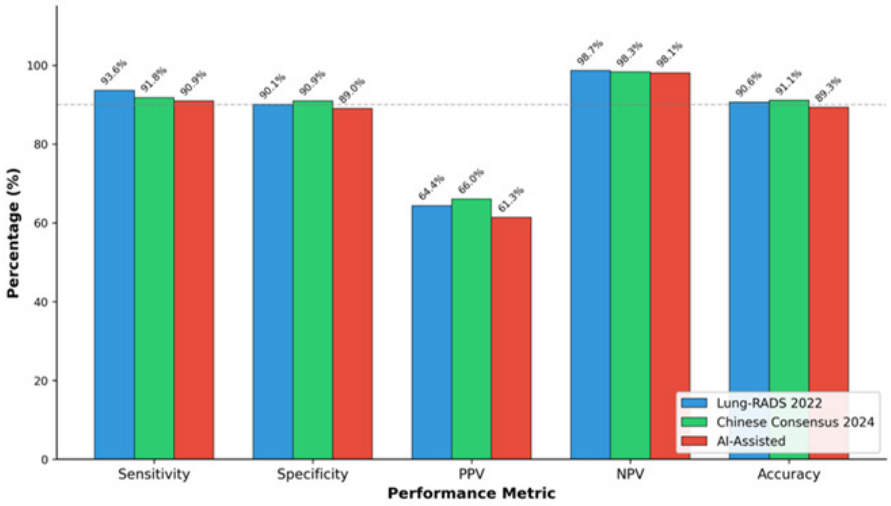

Figure 3: Comparative diagnostic performance metrics across the three assessment methods.

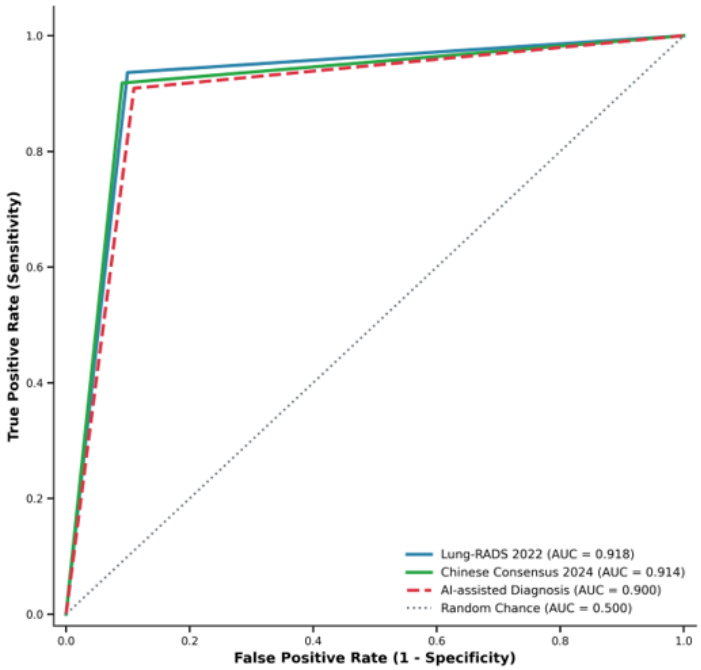

Figure 4: Receiver operating characteristic (ROC) curves comparing diagnostic performance of Lung-RADS 2022, Chinese Expert Consensus 2024, and AI-assisted diagnosis.

4.4. Agreement Analysis

Inter-method agreement between Lung-RADS 2022 and Chinese Consensus 2024 for malignancy detection yielded a kappa coefficient of 0.971 (χ^2=639.00, P<0.001), signifying substantial concordance. The artificial intelligence system demonstrated moderate agreement with histopathological diagnosis (kappa=0.669), marginally inferior to the performance achieved by both human reader-based classification frameworks. Comprehensive confusion matrices for all three analytical approaches are presented in Figure 5.

4.5. Comparison of Malignant and Benign Nodules

Malignant nodules exhibited statistically significant larger dimensions compared to benign lesions (11.4±5.9mm vs. 9.5±4.6mm; t=3.65, P<0.001). The computed tomography manifestation score was likewise substantially elevated among malignant nodules (7.3±1.5 vs. 4.7±1.6; t=15.71, P<0.001). Significant differences were observed in smoking history distribution between malignant and benign groups (χ^2=77.94, P<0.001). Comparison of nodule characteristics between malignant and benign groups in Figure 6 .

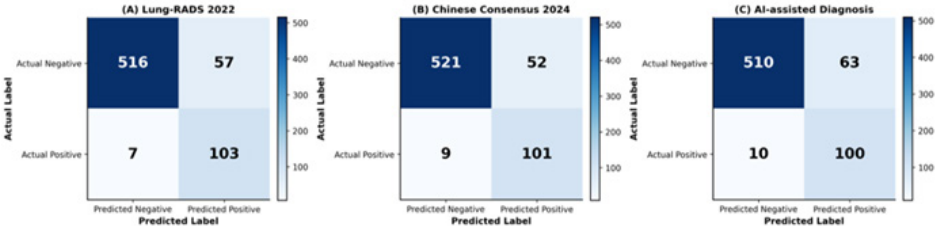

Figure 5: Confusion matrices for (A) Lung-RADS 2022, (B) Chinese Expert Consensus 2024, and (C) AI-assisted diagnosis.

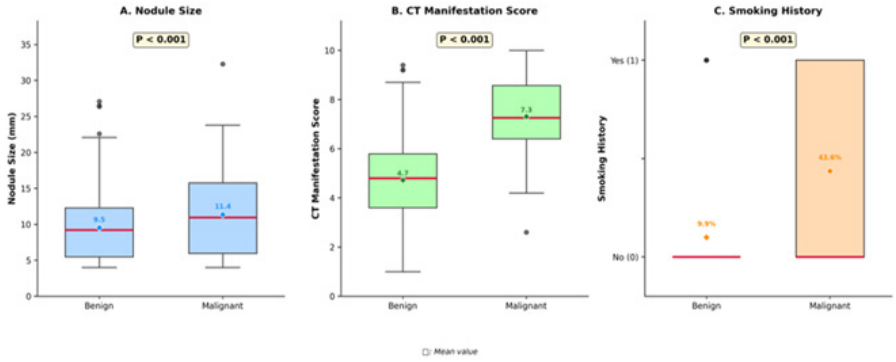

Figure 6: Comparison of nodule characteristics between malignant and benign groups.

4.6. Comparative Analysis of Typical Cases

A: Chest CT of a 45-year-old male with 15-year smoking history showed an 8-mm right lung ground-glass nodule (GGN, arrow). Empirically diagnosed as benign inflammatory nodule without follow-up pre-standardization.

B: CT recheck 6 months later (aggravated cough) revealed nodule enlargement to 12 mm (arrow); pathology confirmed stage IB lung adenocarcinoma. Delayed intervention led to surgery + adjuvant therapy with compromised prognosis. This nodule should be Lung-RADS®2022 Category 4A, requiring 3-month LDCT follow-up per 2024 Chinese Pulmonary Nodule Consensus for early management.

A: Chest CT of a 42-year-old female (non-smoker, past tuberculosis) showed a 7-mm right lung subsolid nodule (SSN, solid component < 6 mm, arrow). Post-standardization, it was categorized as Lung-RADS®2022 Category 3; 6-month follow-up was recommended per 2024 Chinese Consensus (considering tuberculosis history), with patient educated to avoid anxiety.

B: Regular follow-up confirmed stable nodule (arrow); ongoing surveillance avoided overtreatment.

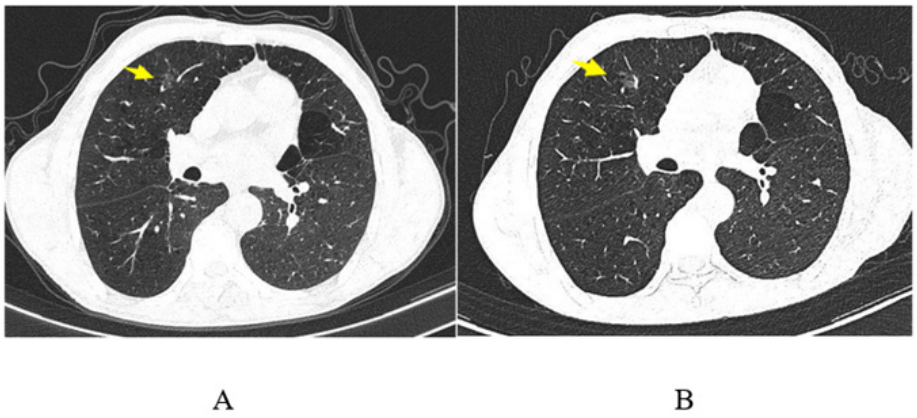

Figure 7: Imaging of a misdiagnosed case pre-standardized assessment.

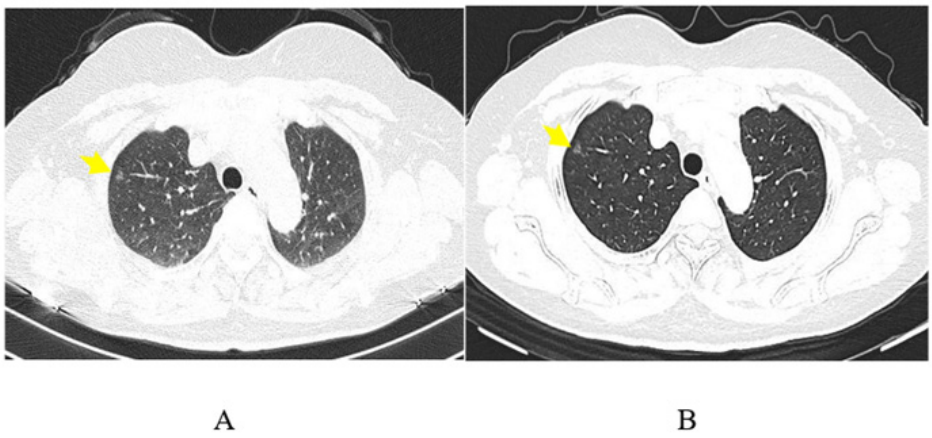

Figure 8: Imaging of a precisely evaluated case post-standardized assessment.

5. Discussion

5.1. Principal Findings

This dual-guideline validation study marks the first comprehensive comparison and validation of Lung-RADS 2022 and the Chinese Expert Consensus 2024 in an East African population with high incidence of infectious pulmonary diseases. Key findings are summarized below: (1) Both classification systems demonstrated robust diagnostic efficacy, with sensitivity over 91% and negative predictive value above 98%; (2) Lung-RADS 2022 achieved marginally higher sensitivity (93.6% vs 91.8%), while the Chinese Expert Consensus 2024 showed slightly superior specificity (90.9% vs 90.1%); (3) AI-aided diagnosis yielded sensitivity comparable to human interpretation but lower specificity; (4) Malignant nodules were significantly larger in volume and had higher computed tomography (CT) scores than benign counterparts, with statistical significance ($P<0.001$).

5.2. Comparison with Previous Studies

Lung-RADS diagnostic performance has been widely validated across diverse global cohorts. Pinsky et al.'s analysis of National Lung Screening Trial data reported that Lung-RADS exhibited 80.8% sensitivity and 88.6% specificity for lung cancer detection [11]. In the present study, Lung-RADS sensitivity reached 93.6%, substantially exceeding this benchmark. This discrepancy is likely attributable to cohort-specific features: our hospital-based cohort had a 16.1% prevalence of malignant lesions, whereas population-based screening studies typically report 1%–5% prevalence [2,11].

Contemporary validation studies on Lung-RADS 2022 have reported variable outcomes. McKee et al. assessed Lung-RADS 2022 in 5,714 U.S. screening participants, documenting 94.4% sensitivity and 89.2% specificity—findings closely aligned with ours [12]. Similarly, Yang et al.'s validation in Chinese populations demonstrated 92.1% sensitivity and 91.3% specificity, confirming the classification system's stable diagnostic performance across ethnic groups [13].

As a newly released guideline, the Chinese Expert Consensus 2024 lacks sufficient external validation data. However, earlier versions of Chinese guidelines have been validated in Asian populations, with sensitivity ranging from 88% to 93% and specificity from 85% to 92% [14,15]. Our study extends this evidence by verifying comparable diagnostic performance in African populations, indicating that the core principle of risk stratification based on nodule size and morphological features retains universal applicability despite differences in disease epidemiology.

The AI-aided diagnostic system employed herein achieved 90.9% sensitivity and 89.0% specificity, consistent with recent meta-analyses showing pooled sensitivity of 89%–92% and pooled specificity of 85%–88% for deep learning-based nodule diagnosis [16,17]. Its slightly inferior performance relative to human interpretation may stem from the study's clinical context: high prevalence of infectious granulomatous lesions in the study population, and differentiating these from malignant nodules is inherently clinically challenging [18].

5.3. Uniqueness of the East African Setting

Epidemiological features of Pemba Island profoundly influence pulmonary nodule assessment. This region bears one of the world's heaviest tuberculosis burdens; World Health Organization data indicate a tuberculosis prevalence of 340 per 100,000 population in Tanzania [19]. Additionally, pulmonary lesions caused by parasitic infections such as paragonimiasis and schistosomiasis may mimic malignant nodules on imaging, further complicating diagnosis [20].

Benign nodules accounted for 83.9% of cases in this study, underscoring the diagnostic challenges in this region. Notably, false positive rates of both classification systems (9.9% for Lung-RADS, 9.1% for the Chinese Expert Consensus) were comparable to or lower than those reported in Western, American and Asian studies. This confirms that both systems maintain favourable specificity even amid high infectious disease prevalence [11,12,13].

These findings hold significant clinical relevance: both classification systems achieved negative predictive values exceeding 98%, meaning negative diagnoses can reliably rule out malignancy. This is particularly critical in resource-limited settings where pathological confirmation is often difficult to obtain, and the conclusion may help reduce unnecessary invasive procedures.

5.4. Comparison between Lung-RADS 2022 and the Chinese Expert Consensus 2024

In our cohort, the two classification systems showed overall comparable diagnostic performance, with overlapping confidence intervals for most evaluation metrics. Lung-RADS 2022's slightly higher sensitivity may reflect its more granular classification, particularly Category 4X which specifically categorizes nodules with additional suspicious features beyond size [3,4]. In contrast, the Chinese Expert Consensus 2024's marginally superior specificity likely stems from its diagnostic logic—emphasizing definitive malignant nodule features rather than relying solely on size assessment [5].

Diagnostic agreement between the two systems was extremely high (Kappa=0.971), indicating consistent final diagnostic and treatment decisions regardless of which system is adopted clinically. This finding enables flexibility in guideline selection: medical institutions can choose based on local resource availability and physician familiarity, rather than being constrained to a single "more diagnostically superior" system.

5.5. Role of AI-Assisted Diagnosis

In this study, the AI diagnostic system's sensitivity was similar to that of the two guideline-based classification systems (90.9% vs 93.6%/91.8%), but with lower specificity (89.0% vs 90.1%/90.9%). This pattern aligns with previous research: in pulmonary nodule diagnosis, AI systems generally offer improved sensitivity but reduced specificity compared to human interpretation [16,17].

Amid the high infectious disease burden in this study, the AI system's lower specificity may result from mainstream deep learning models being trained primarily on Western or Asian datasets, which inadequately cover imaging manifestations of common granulomatous diseases in African populations. This creates inherent difficulties in differentiating malignant nodules from infectious lesions [18]. Nevertheless, the AI system's overall diagnostic accuracy (89.3%) was on par with human interpretation (90.6%/91.1%), confirming its value as an auxiliary tool-especially for preliminary triage in areas with insufficient radiology professionals.

5.6. Clinical Implications

Our findings offer multiple implications for clinical practice in resource-limited settings: (1) Both international (Lung-RADS) and Asian (Chinese Expert Consensus) guidelines can be effectively implemented in East African populations; (2) Both achieve high negative predictive values exceeding 98%, supporting conservative management of negative cases to reduce medical costs and alleviate patient anxiety; (3) Regardless of disease epidemiological context, nodule size and CT score remain reliable indicators for differentiating benign and malignant nodules; (4) AI-aided diagnosis can serve as an efficient triage tool, though final clinical decisions must integrate comprehensive clinical context.

5.7. Study Strengths

This study has several notable strengths: (1) It is the first to simultaneously conduct comprehensive validation of both Lung-RADS 2022 and the Chinese Expert Consensus 2024 in African populations; (2) Pathological biopsy or rigorous imaging follow-up was used as the diagnostic gold standard; (3) It performed head-to-head comparison of diagnostic performance between two human interpretation-based classification systems and AI-aided diagnosis; (4) The sample size was adequate, including 110 malignant cases, ensuring robust statistical analysis; (5) The study report strictly adhered to the Standards for Reporting Diagnostic Accuracy Studies 2015 (STARD 2015) [10].

5.8. Study Limitations

Several limitations of this study should be acknowledged: (1) Its retrospective single-center design may limit the generalizability of conclusions to other African populations; (2) The hospital-based cohort had a higher prevalence of malignant lesions than population-based screening programs; (3) Inter-observer variability in guideline application was not formally evaluated; (4) The performance of the AI system used herein may not represent all similar diagnostic tools; (5) The relative homogeneity of CT scanner models used may affect result reproducibility.

5.9. Future Research Directions

Future research should prioritize the following directions: (1) Conduct prospective multi-center validation across diverse African populations; (2) Develop and validate AI diagnostic models specifically trained on African population data; (3) Assess the economic impact of guideline-directed management in resource-limited settings; (4) Integrate clinical and laboratory parameters (including tuberculosis and human immunodeficiency virus status) into risk stratification models; (5) Undertake long-term follow-up studies to clarify the impact of guideline-directed management on patient outcomes.

6. Conclusions

In conclusion, both Lung-RADS 2022 and the Chinese Expert Consensus 2024 demonstrated excellent diagnostic performance for pulmonary nodule screening in East African populations with high infectious disease burden, achieving sensitivity over 91%, specificity above 90%, and negative predictive value exceeding 98%. The extremely high diagnostic agreement between the two systems (Kappa=0.971) supports their interchangeable use in clinical practice. AI-aided diagnosis showed sensitivity comparable to the two guidelines but lower specificity. This study confirms the applicability of international and Asian guidelines in resource-limited, high-infectious-disease-prevalence settings, providing strong evidence for promoting their implementation in Africa to improve early lung cancer detection.

7. Funding

The authors declare that financial support was received for the research and/or publication of this article. This work was supported by the Science and Technology Project of Lianyungang

City (No. SF2311), the Aging Health Research Project of Lianyungang City (No. L202318), and the Health Technology Project of Lianyungang City (No. 202219).

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