274P - AI/ML-BASED LUNG CANCER DETECTION AND CHARACTERIZATION FOR LUNG CANCER SCREENING: RESULTS FROM THE REALITY STUDY ON EARLY-STAGE LUNG CANCER

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BACKGROUND

AI-assisted radiological reading is entering clinical practice, potentially revolutionizing lesion characterization and early lung cancer detection. Tumor size and cancer stage at diagnosis are key determinants of survival: small, early-stage cancers are more responsive to treatment, with better prognoses. An AI/ML-Based computer assisted detection and diagnostic algorithm (CADe/CADx), was designed to assist the detection and characterization of suspicious lung nodules during lung cancer screening (LCS).

We present a subset of the pivotal REALITY Study results focusing on cancer stage and cell type.

METHODS

Retrospective cohort study of individuals meeting USPSTF LCS criteria at five academic centers in Europe and the USA.

LDCT exams analyzed with the CADe/CADx; output compared to radiologist consensus. Reference standard proven via histopathology or ≥12 months stability.

AI/ML-Based CADe/CADx developed so that suspicious nodules presented on the results report should receive additional follow-up.

FIGURES OF INTEREST

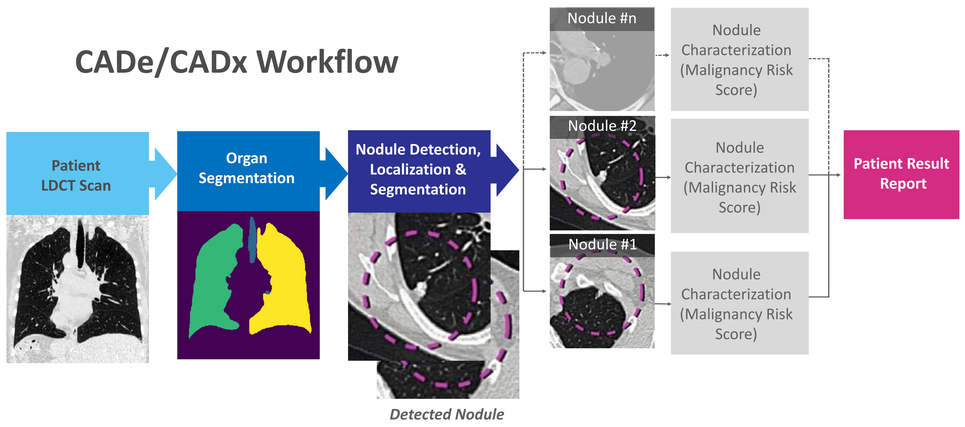

Figure 1: Presentation of the global workflow of the CADe/CADx for lesion prediction, with CADe 3D convolutional neural network (CNN) detection and lung segmentation on the left, and with nodule segmentation and CADx on the right. At the end a results report is generated.

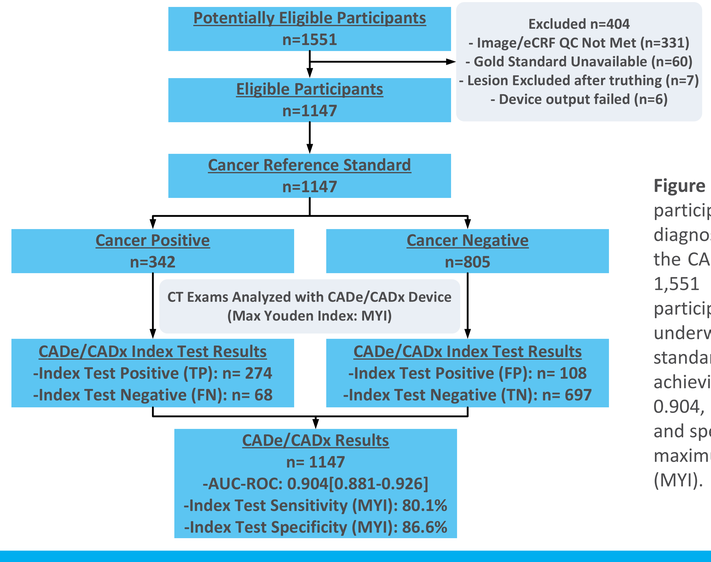

Figure 2: Flowchart of participant selection and diagnostic performance of the CADe/CADx algorithm. Of 1,551 potentially eligible participants, 1,147 underwent the reference standard, with the device achieving an AUC-ROC of 0.904, sensitivity of 80.1%, and specificity of 86.6% at the maximum Youden Index (MYI).

RESULTS

Category	Value
Total Patients (Count)	• 1147
Patient Region (Count, % Total)	• EU: 336, 29.29% • USA: 811, 70.71%
Cancer Diagnosis (Count, % Total)	• Non-Cancer: 805, 70.18% • Cancer: 342, 29.82%
Average Age (Years, SD)	• Entire Cohort: 64.94 ± 6.35 • Non-Cancer: 63.95 ± 6.30 • Cancer: 67.26 ± 5.83
Nodule Size (mm, SD)	• Non-Cancer: 6.37 ± 2.91 • Cancer: 14.91 ± 5.66
Cancer Stage (Count)	• Stage I: 219 • Stage II-IV: 56 • Not Available: 67
Cancer T-category (Count)	• T1: 227 • T2-4: 43 • Not Available: 72
Lung Cancer Cell Type (Count)	• NSCLC: 213 • Other Cell Type (SCLC Included): 64 • Not Available: 65

Table 1: Study Participants.

Lung Cancer Cell Type	AUC	Sensitivity (Cancer Recall Rate)
NSCLC	0.908	97.2%
Other Lung Cancer Cell Types	0.853	89.1%

Table 2: AUC for correct lesion characterization and cancer recall rate (sensitivity) according to cancer cell type.

Class	Sub-Class	Sensitivity (Cancer Recall Rate)	False Positive Detections Per Exam
Cancer Stage	Stage I	96.8%	0.80 FP/ Scan
	Stage II-IV	98.2%	0.86 FP/Scan
Cancer T-Category	T1	96.5%	0.80 FP/Scan
	T2-4	100%	0.86 FP/SCan

Table 3: Cancer recall rate and false positive marks per examination for patients according to cancer stage and cancer t-category

CONCLUSIONS

The AI/ML-Based CADe/CADx showed high performance in detecting early lung cancer, high sensitivity for cancers of different stage, T-category and cell type, excellent cancer recall rate (>96.5%) on all cancer stages and t-categories. This CADe/CADx can assist in the accurate follow-up of suspicious lung nodules, optimizing the management of patients in lung cancer screening.

CONFLICTS OF INTEREST

Presenter R. OSAROGIAGBON: consultancies and advisory Median Technologies.

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