13190 - AI-ASSISTED LUNG CANCER SCREENING: RESULTS FROM REALITY, A PIVOTAL VALIDATION STUDY OF AN AI/ML-BASED SOFTWARE

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BACKGROUND

Lung cancer remains the number one cause of cancer mortality in the United States, often diagnosed at advanced stage with poor 5-year survival.

Recently, the development and clinical implementation of AI in patient management has been shown to equal or surpass pulmonary nodule detection and characterization performance of radiologists.

Here we present a pivotal standalone validation study of an AI/ML-based software that detects, localizes, segments, and characterizes pulmonary nodules between 4-30 mm present on low-dose CT screening exams.

METHODS

Retrospective cohort study of 1147 patients enriched for cancer prevalence (29.8% cancer) meeting the USPSTF criteria for LCS with LDCT screening exams.

To demonstrate software stability on technical and clinical subclasses (e.g. size, shape), the dataset was further enriched such that each subclass was sufficiently represented.

Reference standard was established via histopathology or ≥12month stability. Sensitivity, specificity, and FP/scan values are presented at the maximum Youden Index (MYI).

FIGURES OF INTEREST

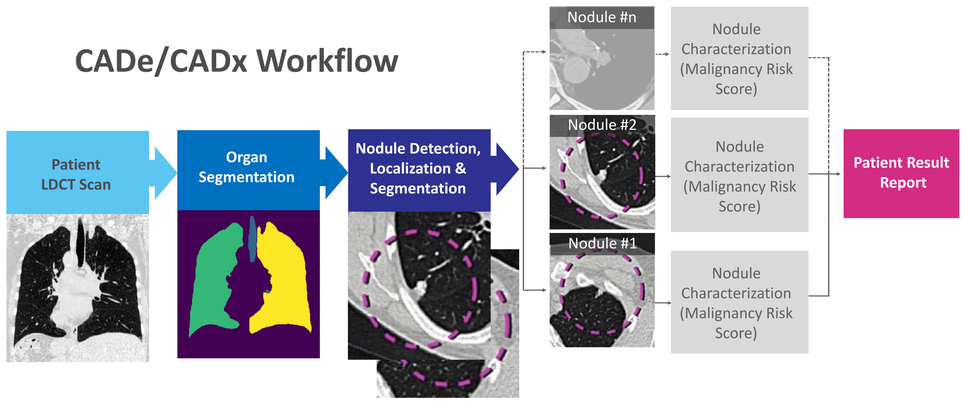

Figure 1: Presentation of the global workflow of the CADe/CADx for lesion prediction, with CADe 3D convolutional neural network (CNN) detection and lung segmentation on the left, and with nodule segmentation and CADx on the right. At the end a results report is generated.

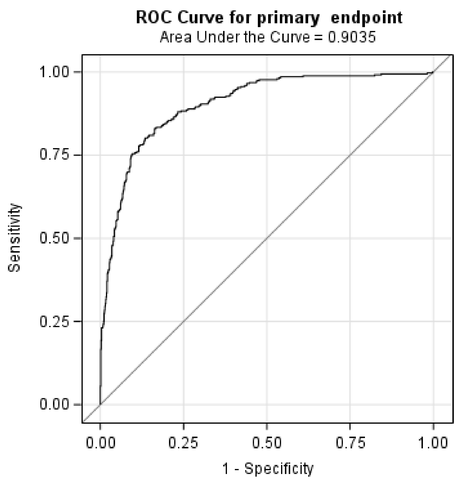

Figure 2: Patient level AUC was 0.904 [95% CI, 0.881-0.926], with sensitivity and specificity of 80.1% and 86.6%.

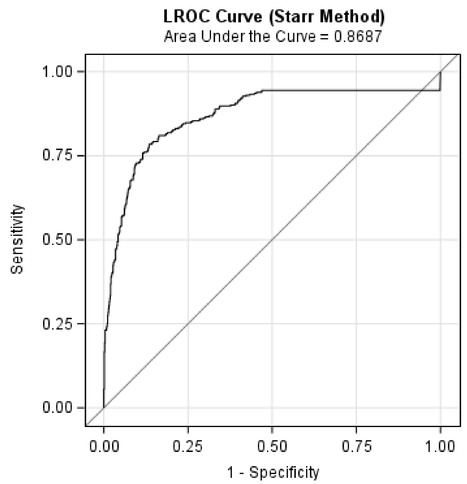

Figure 3: AU-LROC was 0.869 with a sensitivity of 78.4% and specificity 86.6% at the MYI

RESULTS

Patient Sub Class	Total	Cancer	Non-Cancer
EU	336 (29.3%)	95 (27.8%)	241 (29.9%)
USA	811 (70.7%)	247 (72.2%)	564 (70.1%)
Male	594 (51.8%)	188 (55%)	406 (50.4%)
Female	553 (48.2%)	154 (45%)	399 (49.6%)
Largest nodule 4-10mm	750 (65.4%)	70 (20.5%)	680 (84.5%)
Largest Nodule 10-20mm	314 (27.4%)	203 (59.4%)	111 (13.8%)
Largest Nodule 20-30mm	83 (7.2%)	69 (20.2%)	14 (1.7%)
With Solid Nodule(s) Only	738 (64.3%)	245 (71.6%)	493 (61.2%)
With At least one Part-Solid Nodule(s)	215 (18.7%)	97 (28.4%)	118 (14.7%)
Patient Without Nodule(s)	194 (16.9%)	0 (0%)	194 (24.1%)
With Non-Spiculated Nodule(s) Only	628 (54.8%)	101 (29.5%)	527 (65.5%)
With At least One Spiculated Nodule(s)	325 (28.3%)	241 (70.5%)	84 (10.4%)

Table 1: Study Participants. Of 1,551 potentially eligible participants, 1,147 underwent the reference standard generation and we included in the endpoint analysis.

Class	Sub-Class	AUC	Sensitivity	Specificity
Entire Cohort	N/A	0.904[0.881-0.926]	0.801[0.755-0.842]	0.866[0.840-0.889]
Cancer Stage	Stage I	0.890[0.861-0.920]	0.804 [0.745-0.854]	0.836 [0.809-0.861]
	Stage II-IV	0.909[0.857-0.961]	0.786 [0.656-0.884]	0.909 [0.887-0.928]
Cancer Size	4-10mm	0.834 [0.774-0.894]	0.914 [0.823-0.968]	0.594 [0.556-0.631]

Table 2: Study Participants. AUC, sensitivity and specificity for the entire cohort, per cancer stage and for patients with cancers between 4mm and 10mm.

CONCLUSIONS

The AI/ML-based software demonstrates a high level of performance in a multicenter validation cohort enriched for cancer prevalence, cancer stage, and small non-spiculated cancer nodules, with high sensitivity across nodule size and cancer stage. This AI/ML-based software demonstrated its potential to optimize the detection, localization, characterization and management of small screen-detected nodules leading to earlier diagnosis, more effective therapy, impacting survival of cancer patients.

Disclosures: A. VACHANI: consultancies and advisory Median Technologies.

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