PERFECTING INTELLIGENCE,
TRANSFORMING MEDICINE.

Medical Whitepaper

Lunit

ABOUT US

Lunit, abbreviated from “learning unit,” is a medical AI software company devoted to developing advanced medical image analytics and novel imaging biomarkers via cutting-edge deep learning technology.

Founded in 2013, Lunit has been internationally acknowledged for its advanced, state-of-the-art technology and its application in medical images. Lunit is based in Seoul, South Korea.

MISSION STATEMENT

Lunit’s mission is to empower physicians with clinically actionable insights that foster accurate and cost-efficient diagnosis and treatment through unprecedented AI-powered imaging biomarkers with cutting-edge, world-leading accuracy.

Through our state-of-the-art deep learning technology trained with a vast amount of carefully curated, quality medical data, we would like to become a leader and pioneer in transforming medicine into the next level.

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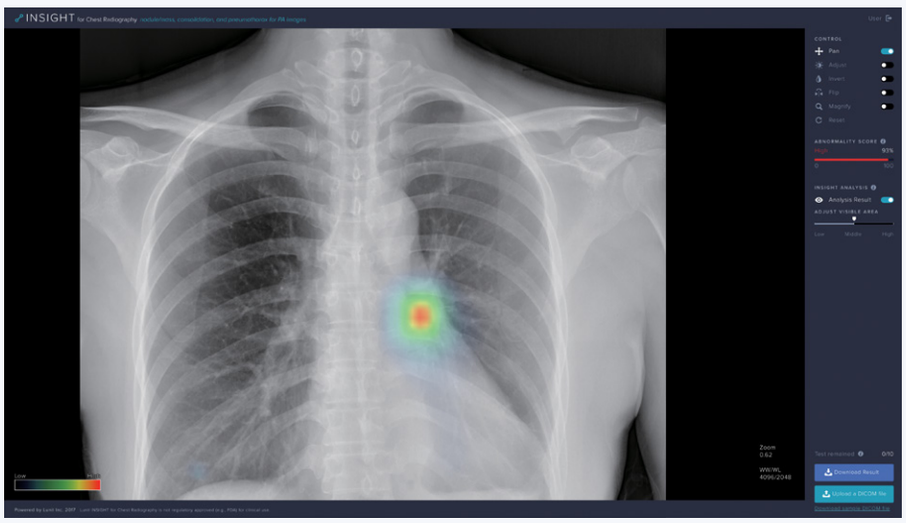


LUNIT INSIGHT FOR CHEST RADIOGRAPHY

Although chest radiography is the most commonly used — 25% of the annual total numbers of diagnostic imaging procedures, thus being the most fundamental imaging test — the interpretive performance is suboptimal, where 20-30% are reported to be missed. The ever growing burden for physicians is intensified with high volume of image to interpret.

Lunit INSIGHT for Chest Radiography is the solution to this problem. With an accuracy level that reaches 97-99%, it detects lung nodule/mass, consolidation and pneumothorax within seconds. *Lunit INSIGHT for Chest Radiography* was trained by over 200,000 chest x-ray images.

Lunit INSIGHT for Chest Radiography has been approved by Korea MFDS (Ministry of Food and Drug Safety) on August 2018. It is expected to get approval by FDA/CE soon.

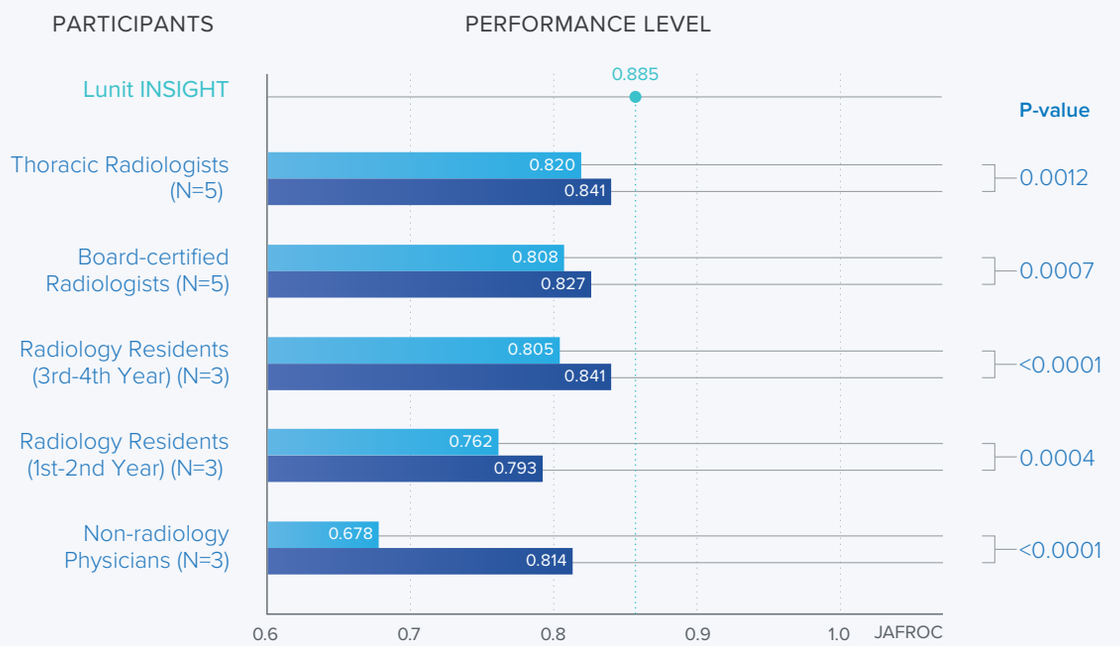
You can login to **https://insight.lunit.io** to freely upload chest x-ray DICOM images and get real-time diagnosis results conducted by Lunit INSIGHT in no time.

READER STUDY : LUNIT INSIGHT FOR CHEST RADIOGRAPHY NODULE DETECTION

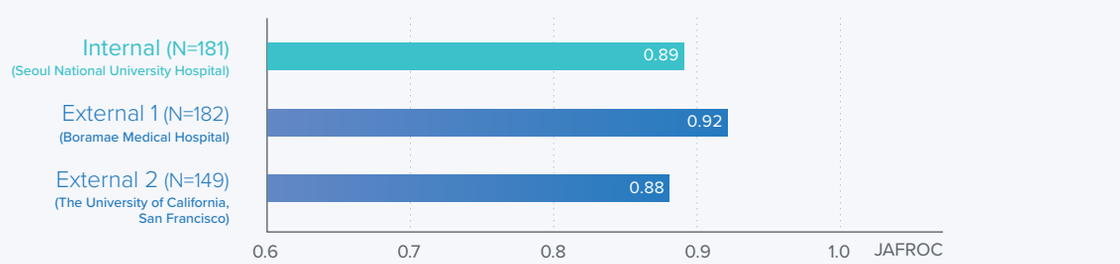
Nam JG*, Park SG*, et al. Development and Validation of Deep Learning-Based Automatic Detection Algorithm for Malignant Pulmonary Nodules on Chest Radiographs. Radiology. 2018 Sep 25:180237.

According to our reader study for detection of lung nodule in chest radiography, the accuracy of Lunit's algorithm was the highest among the entire group of readers, including thoracic radiologists and board-certified radiologists.

It has proven that with *Lunit INSIGHT for Chest Radiography Nodule Detection* as a second reader, physicians of different expertise level showed statistically significant increase in performance in detecting pulmonary nodules in chest x-rays. For non-radiology physicians, the performance level significantly increased up to 20%.



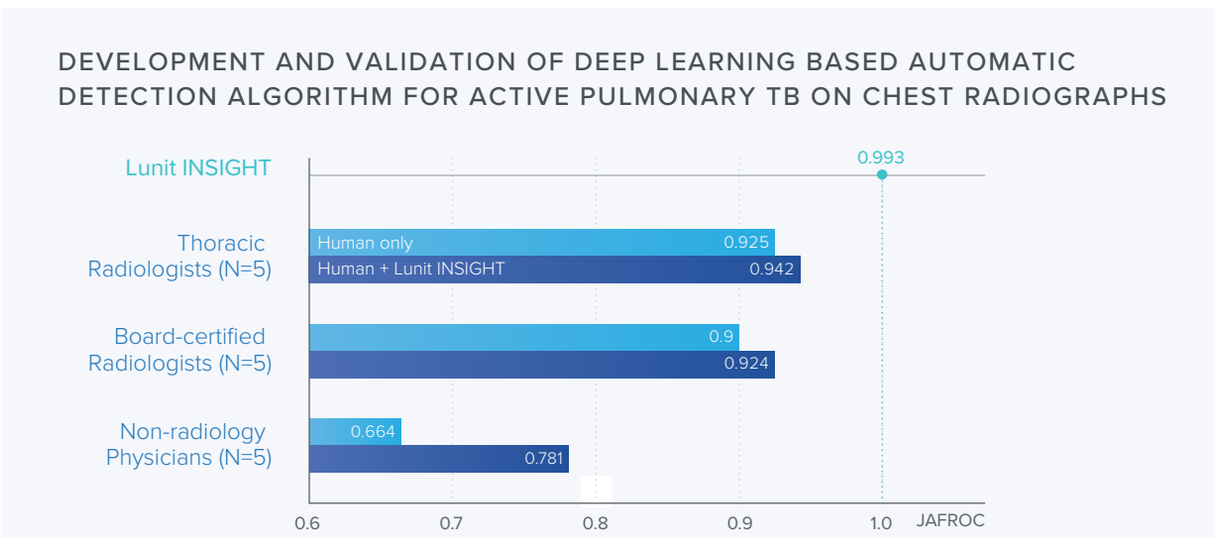
LUNG CANCER EXTERNAL VALIDATION

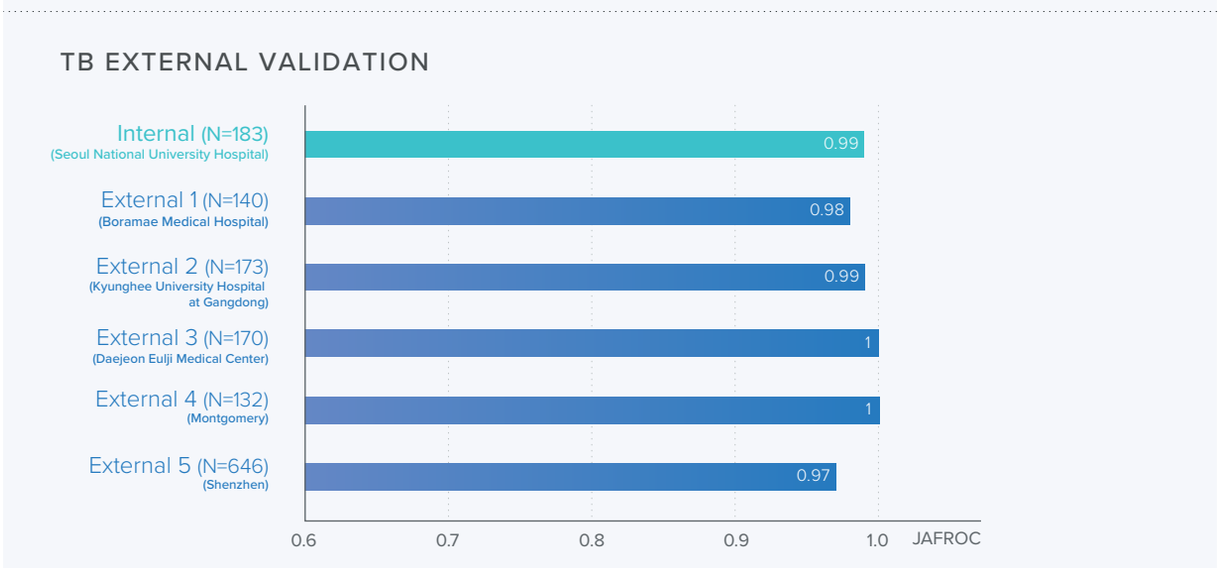


READER STUDY : LUNIT INSIGHT FOR CHEST RADIOGRAPHY TB SCREENING

Hwang EJ*, Park SG*, et al. Development and Validation of a Deep Learning-Based Automatic Detection Algorithm for Active Pulmonary Tuberculosis on Chest Radiographs. Clinical Infectious Diseases. 2018 Nov 12.

The reader study for detection of tuberculosis in chest radiography showed that *Lunit INSIGHT for Chest Radiography TB Screening* recorded the highest accuracy among 15 physicians including thoracic radiologists, non-radiology physicians, and board-certified radiologists.
It has proven that with *Lunit INSIGHT for Chest Radiography TB Screening* as a second reader, physicians showed a statistically significant increase in performance in detecting tuberculosis in chest x-rays.
Moreover, *Lunit INSIGHT for Chest Radiography TB Screening* showed similar performance level with internal validation dataset when validated with external validation dataset from five different institutions, including two public dataset.

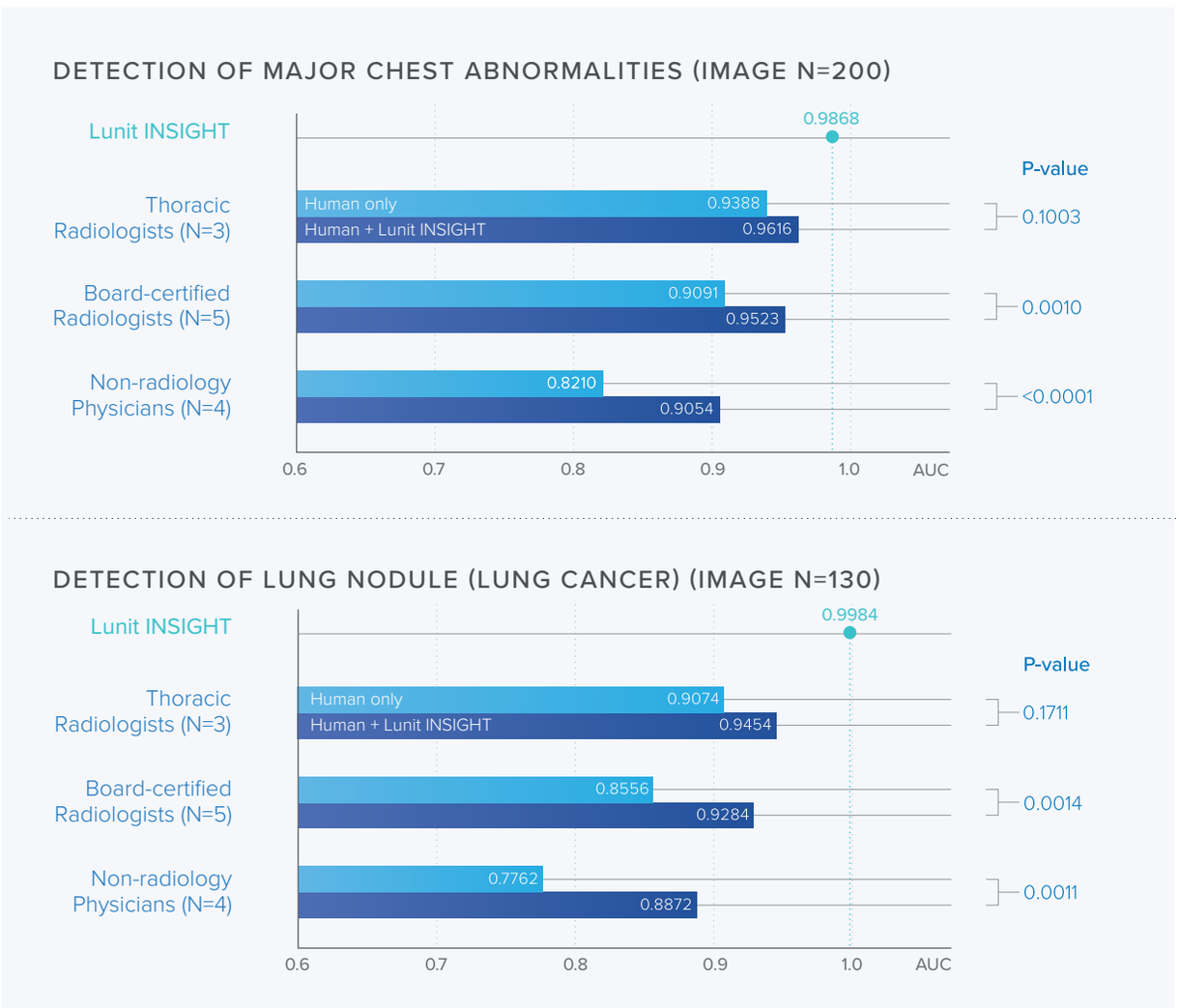




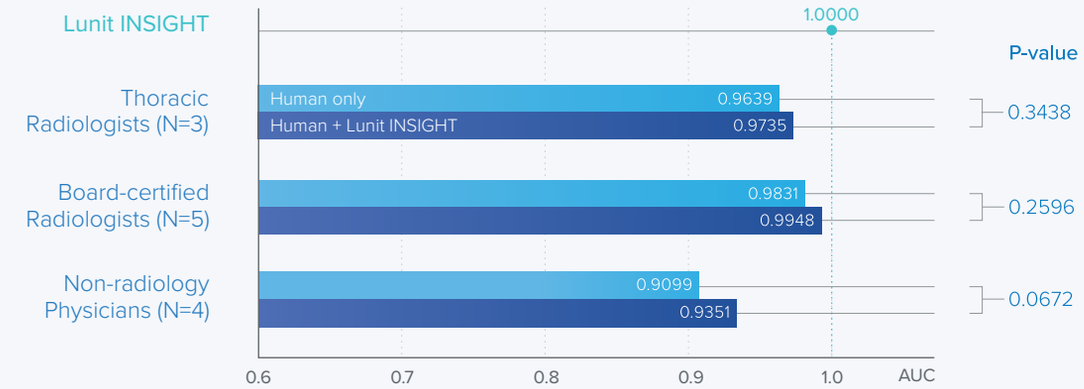
READER STUDY :
LUNIT INSIGHT FOR CHEST RADIOGRAPHY

Performance Validation of a Deep Learning-Based Automatic Detection Algorithm for Major Thoracic Abnormalities on Chest Radiographs, RSNA 2018

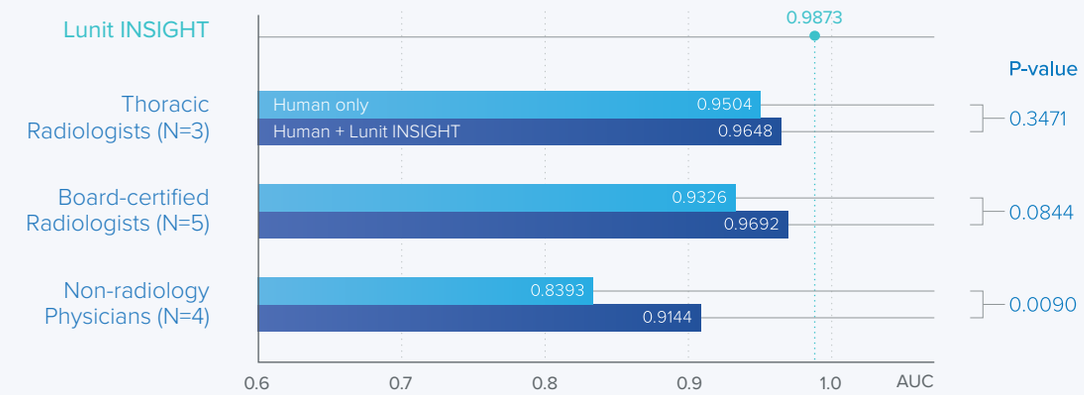
In our efforts to clinically validate the performance level of *Lunit INSIGHT for Chest Radiography*, we have conducted a reader study with Seoul National University Hospital. The results of this preliminary study are shown below, where the detection of major chest abnormalities (nodule/mass, consolidation, pneumothorax) has been tested in comparison to general physicians and radiologists, represented by detection of lung cancer, tuberculosis, pneumonia, and pneumothorax. The ground truth labels for the chest x-ray images used in this study were established by CT exams taken within 1 week or by consensus of an expert panel.



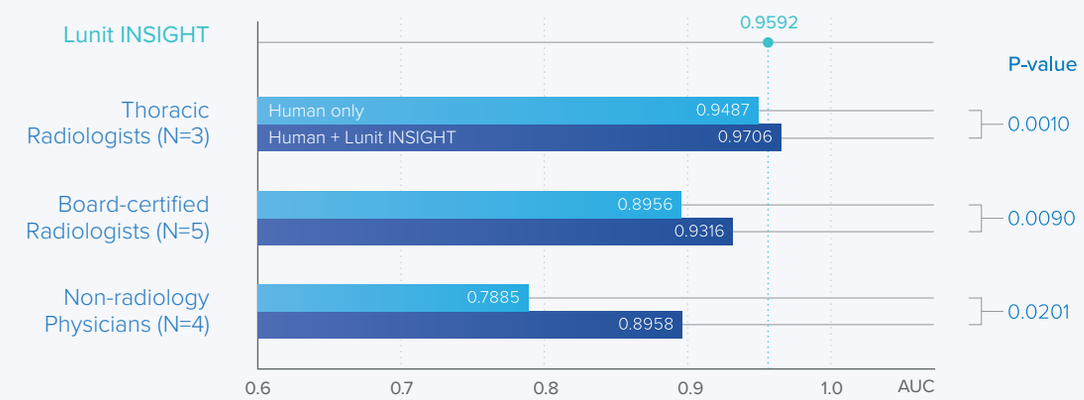
DETECTION OF TUBERCULOSIS (IMAGE N=117)



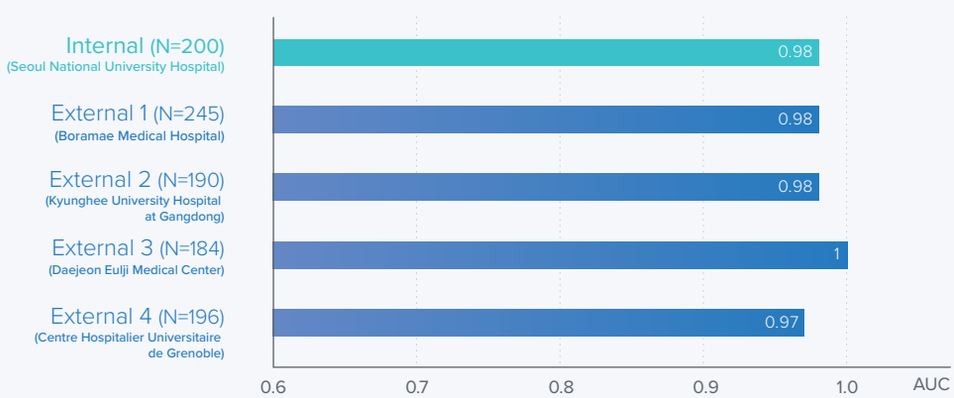
DETECTION OF PNEUMONIA (IMAGE N=123)



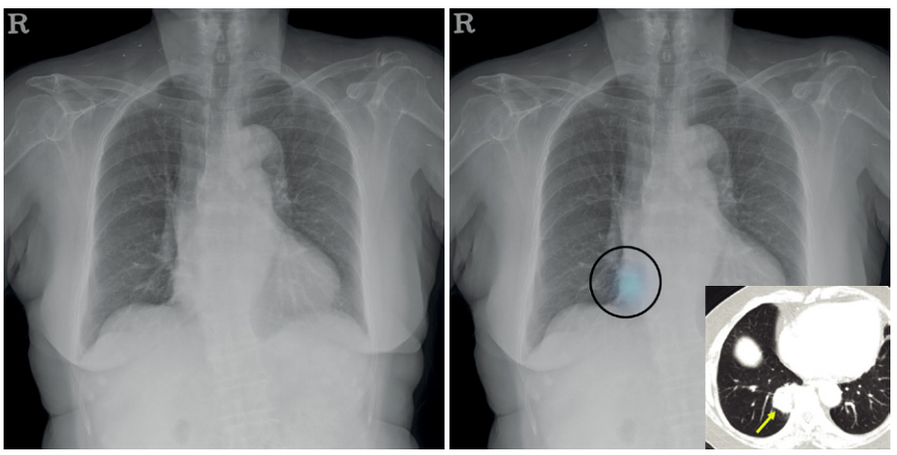
DETECTION OF PNEUMOTHORAX (IMAGE N=121)



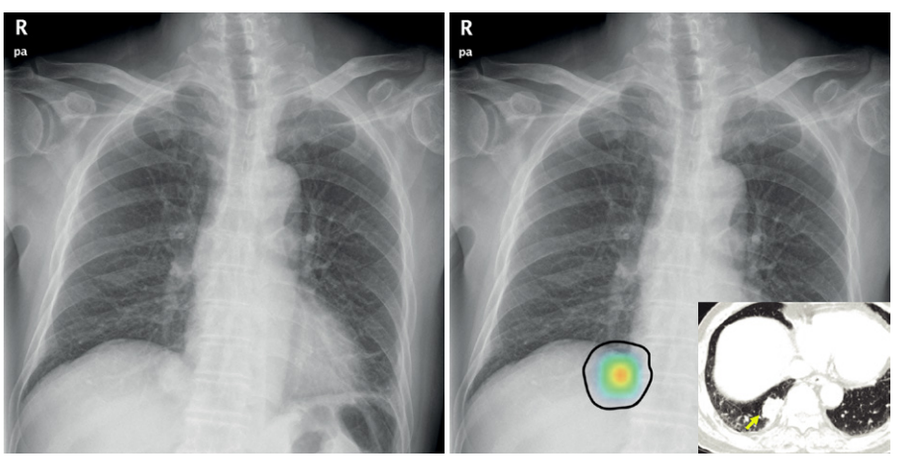
MCA EXTERNAL VALIDATION



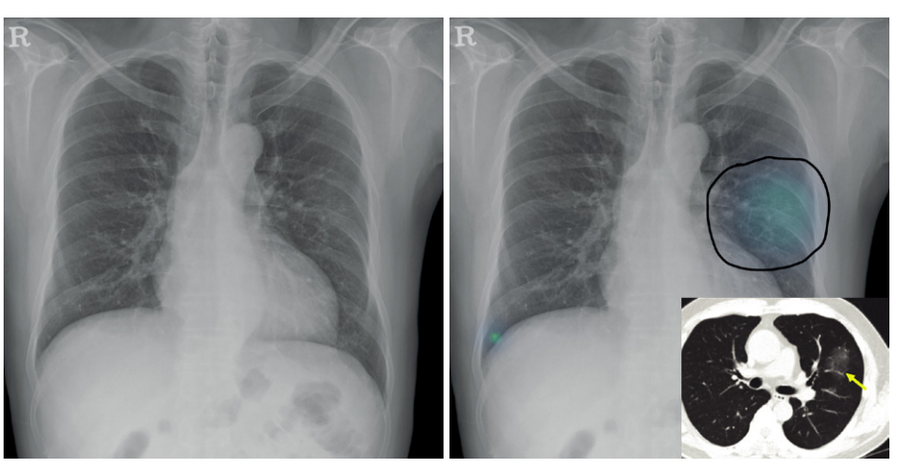
SAMPLE CASES



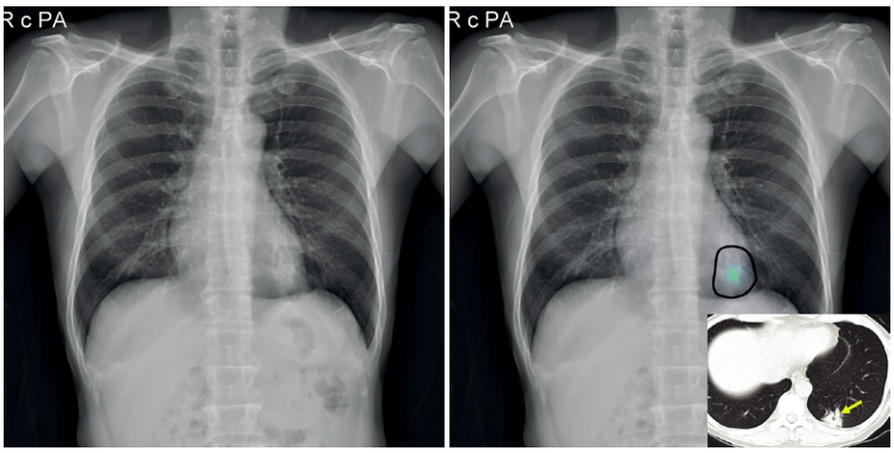
CASE 1 A lung cancer located in the right lower lobe is properly detected by Lunit INSIGHT. Eight out of 10 radiologists missed the lesion during our validation studies.



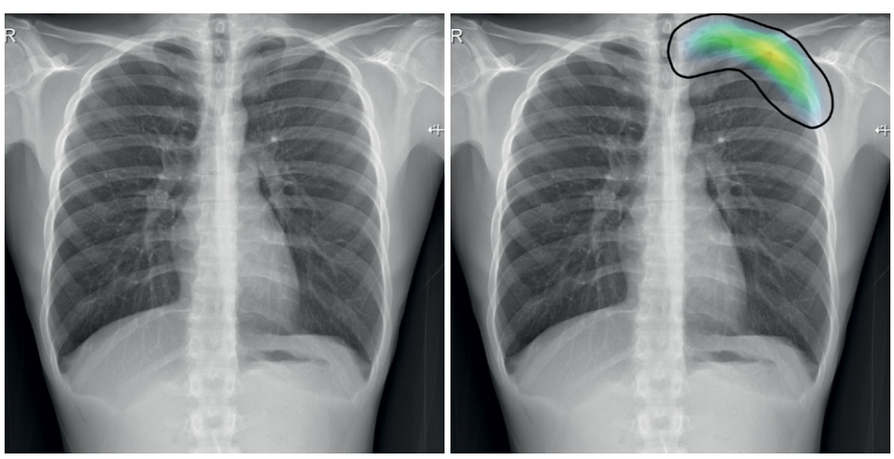
CASE 2 A lung cancer located in the right lower lobe is properly detected by Lunit INSIGHT. Five out of 10 radiologists missed the lesion during our validation studies.



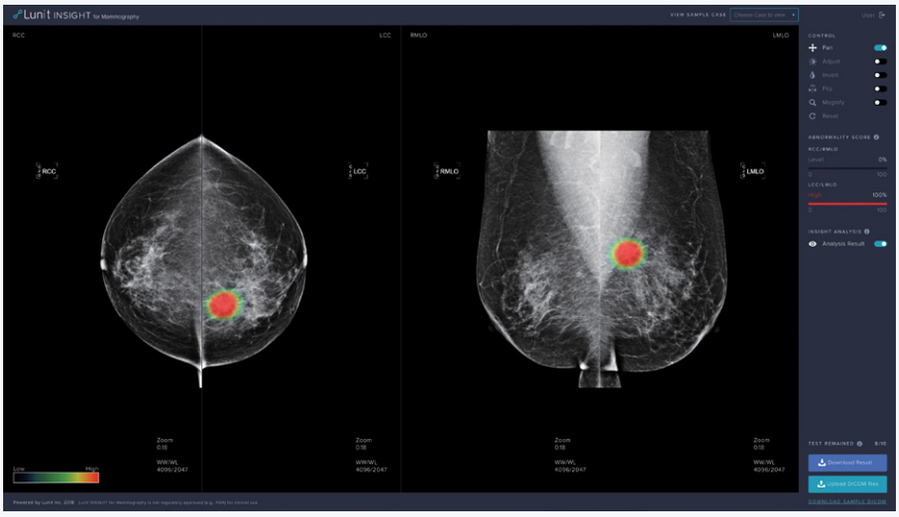
CASE 3 A pneumonia located in the left middle lung area is properly detected by Lunit INSIGHT. Ten out of 10 radiologists missed the lesion during our validation studies.



CASE 4 A tuberculosis located in the left retrocardiac area is properly detected by Lunit INSIGHT. Three of 10 radiologists missed the lesion during our validation studies.



CASE 5 A pneumothorax at left upper lung area is properly detected by Lunit INSIGHT. Five out of 10 radiologists missed the lesion during our validation studies.



LUNIT INSIGHT FOR MAMMOGRAPHY

Breast cancer is one of the most common cancer that takes up 25% of the entire cancer and is the leading cause of death, at 15%, among women worldwide. Screening mammography is the only single modality proven to improve breast cancer survival, with a mortality reduction rate of around 20%.

However, accuracy of screening mammography is low, with false negative rates of 10-30% and false positive rates around 95%. Proportion of breast specialists reading screening mammograms is also low.

Lunit INSIGHT for Mammography provides solution to this problem by detecting breast cancer lesions with 97% accuracy within seconds after uploading the patient's mammography image to our software. *Lunit INSIGHT for Mammography* was trained by over 200,000 mammography cases of which approximately 50,000 cases were from breast cancer patients.

Ultimately, our solution is expected to help radiologists make better decisions to recall a patient or not.

Lunit INSIGHT for Mammography is expected to get US Food and Drug Administration (FDA) and European CE mark approval within 2019.

You can login to **https://insight.lunit.io** to freely upload images and get real-time diagnosis results conducted by Lunit INSIGHT in no time.

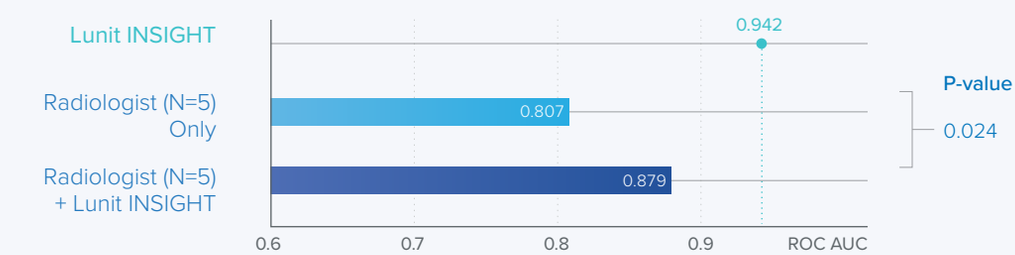
READER STUDY RESULTS

Clinical studies have shown *Lunit INSIGHT for Mammography* to enable radiologists to perform significantly better in detecting malignant cases, with increased performance level upto 10%.

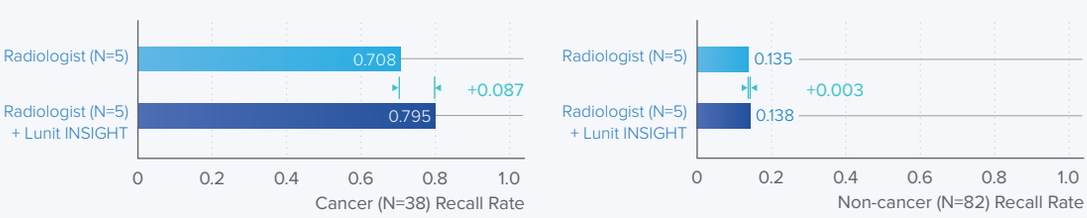
When *Lunit INSIGHT for Mammography* was directly compared to traditional CAD, its performance level was superior by a large margin, especially in terms of specificity, which has been the major issue with traditional CAD.

Yonsei University Severance Hospital, November 2017 (RSNA 2018)

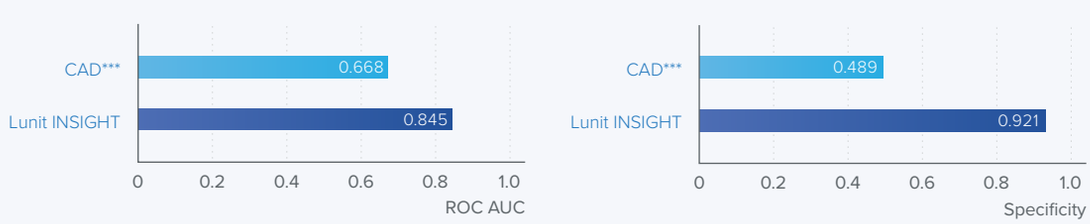
COMPARISON WITH RADIOLOGISTS FOR CANCER DETECTION* (EXAMS N=120)



COMPARISON WITH RADIOLOGISTS FOR RECALL RATE** (EXAMS N=120)

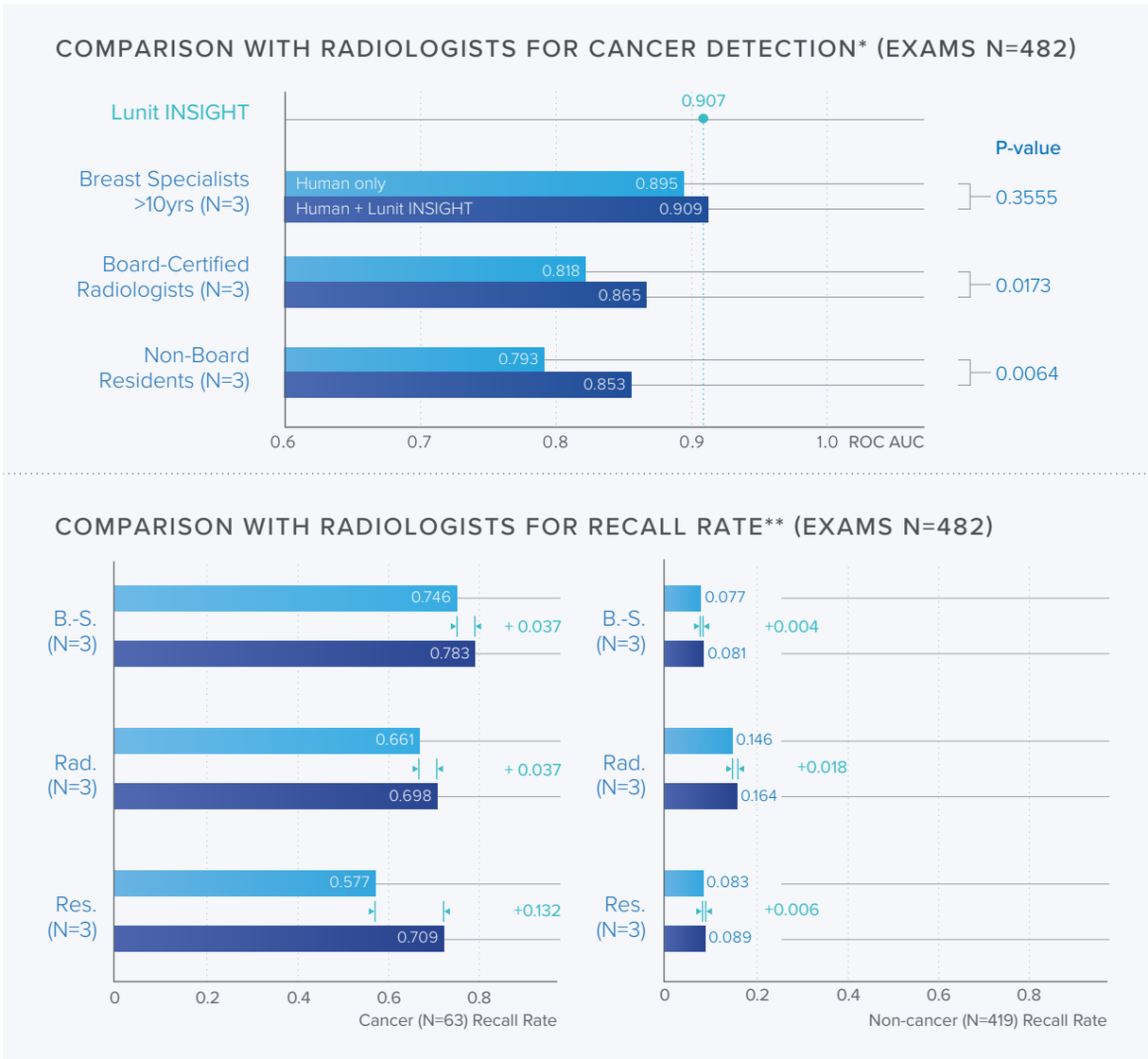


COMPARISON WITH CAD*** FOR CANCER DETECTION (EXAMS N=76)



* Based on reader's rating (DMIST 7pt score) for likelihood of malignancy (LOM) w/ and w/o Lunit INSIGHT
** Based on reader's binary decision whether each case should be recalled w/ and w/o Lunit INSIGHT
*** CAD denotes analysis results from a commercially available computer aided detection software

National Cancer Center, November 2018 (Pilot Study)

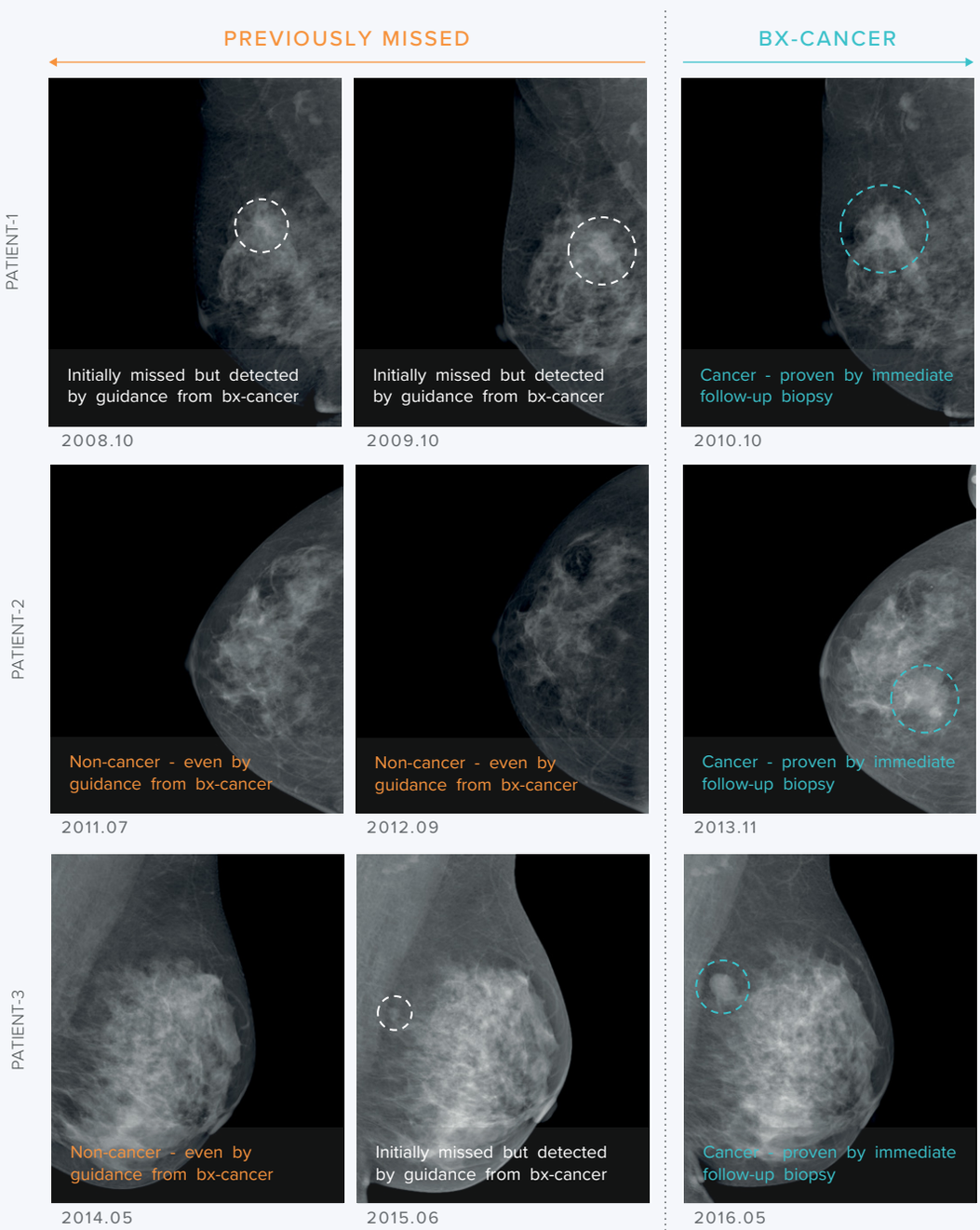


* Based on reader's rating (DMIST 7pt score) for likelihood of malignancy (LOM) w/ and w/o Lunit INSIGHT
** Based on reader's binary decision whether each case should be recalled w/ and w/o Lunit INSIGHT

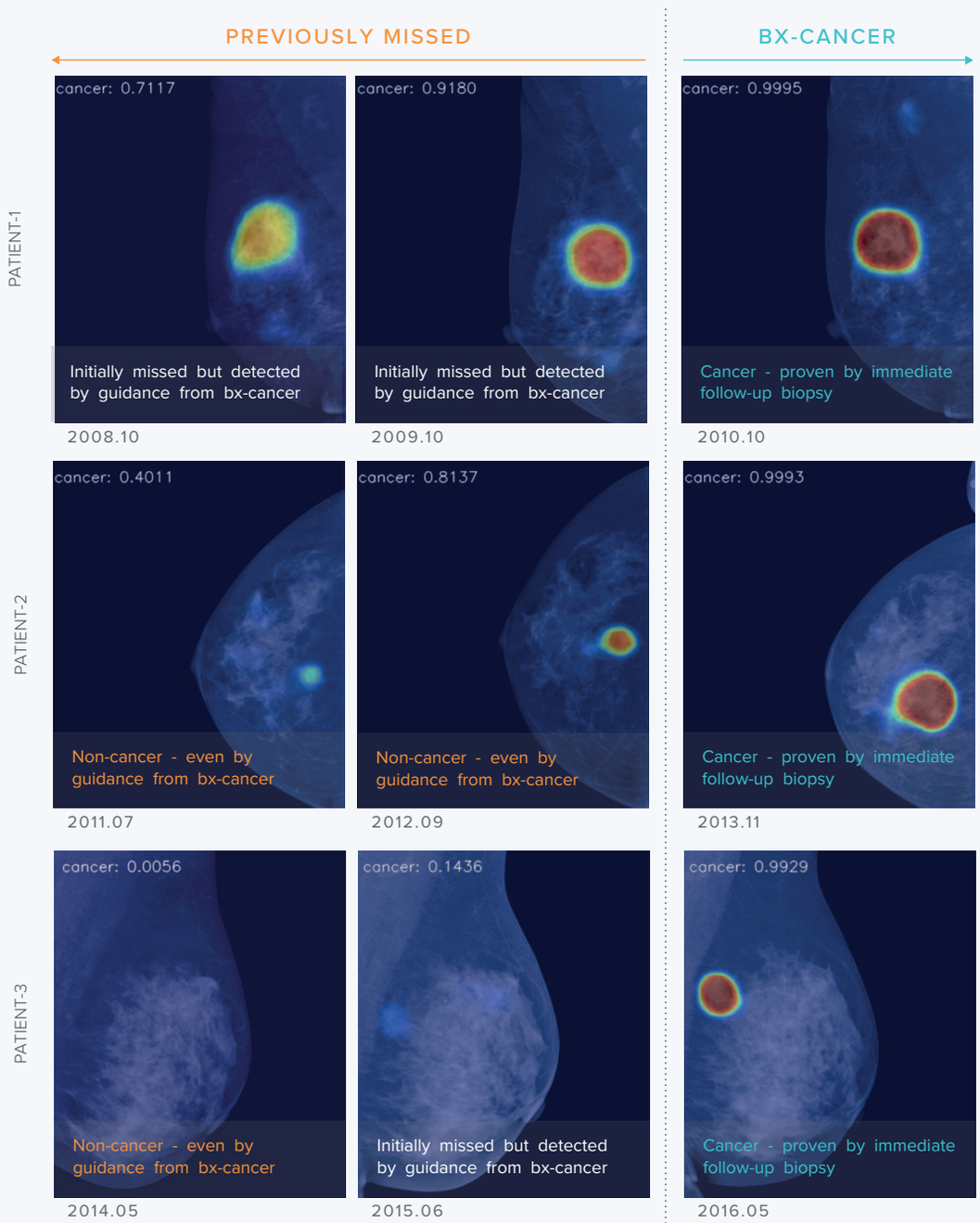
EARLY-STAGE CANCER ANALYSIS

Below image data, on pages 14-15, show the performance evaluation of *Lunit INSIGHT for Mammography* in terms of early-stage cancer detection. Each example consists of biopsy-proven cancer case and its previous studies. Image set on the left (p.14) show the ground truth and its retrospective review made by radiologists, which were initially missed. The image set on the right side (p.15) show the same cases analyzed by *Lunit INSIGHT for Mammography* and its detection of malignant lesions presented in heatmaps.

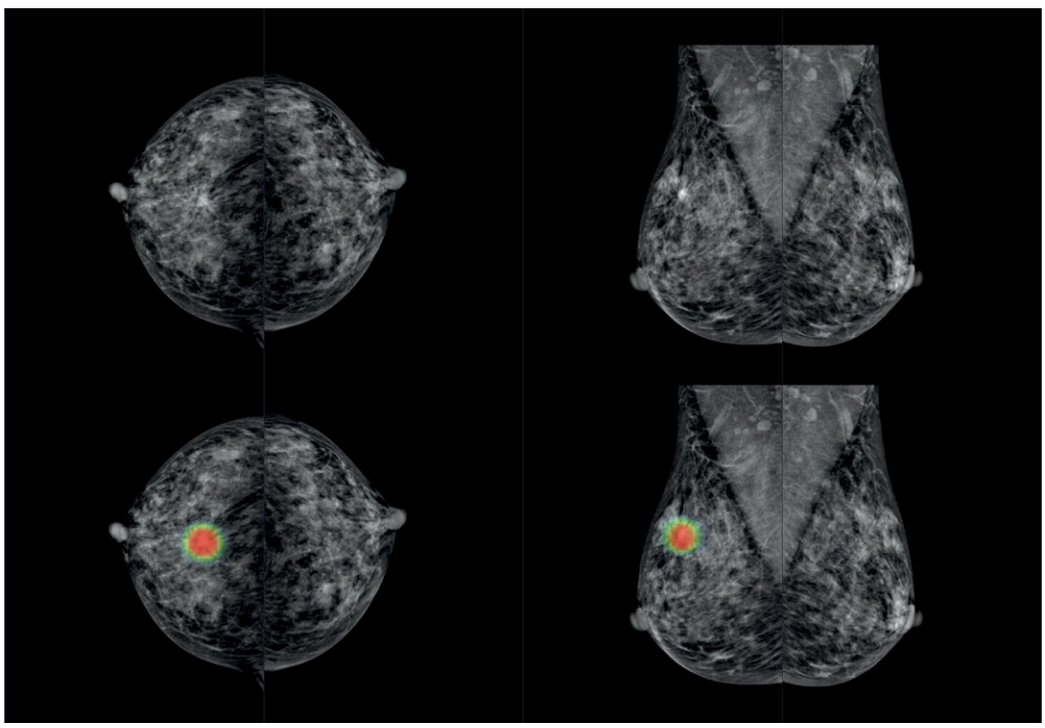
GROUND TRUTH



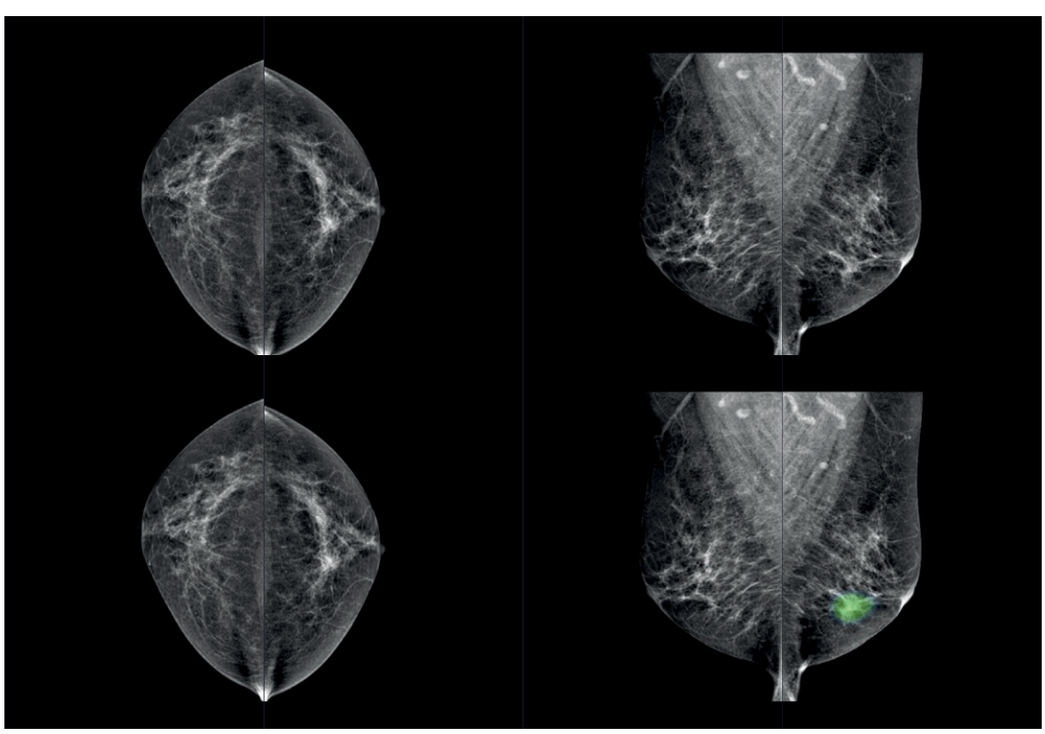
LUNIT INSIGHT FOR MAMMOGRAPHY



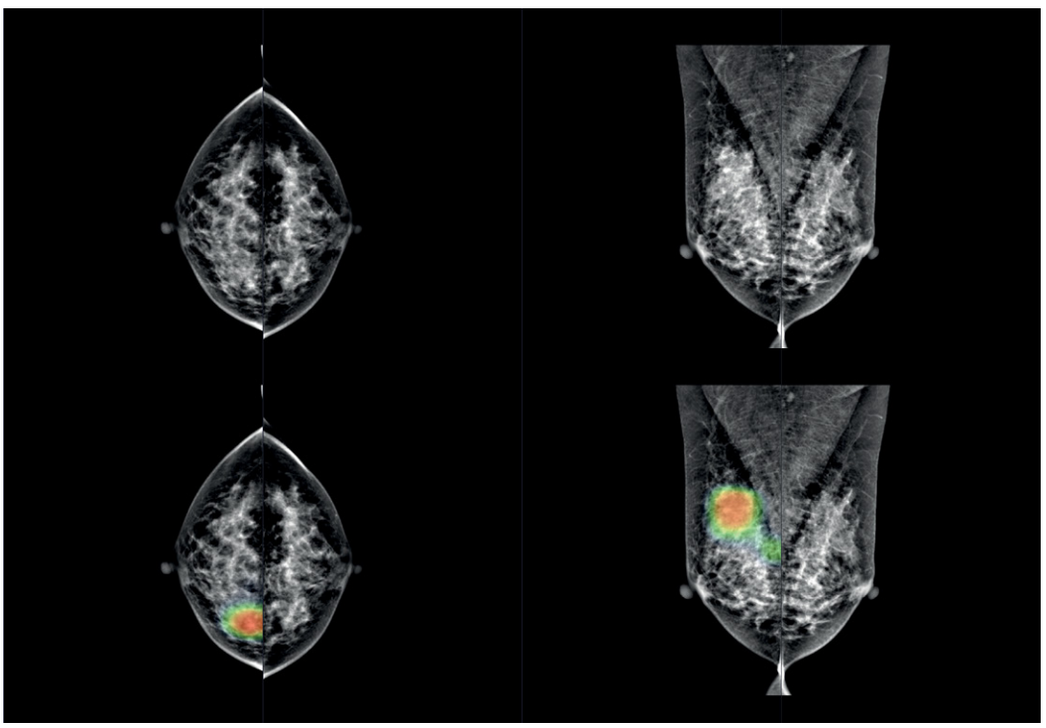
SAMPLE CASES



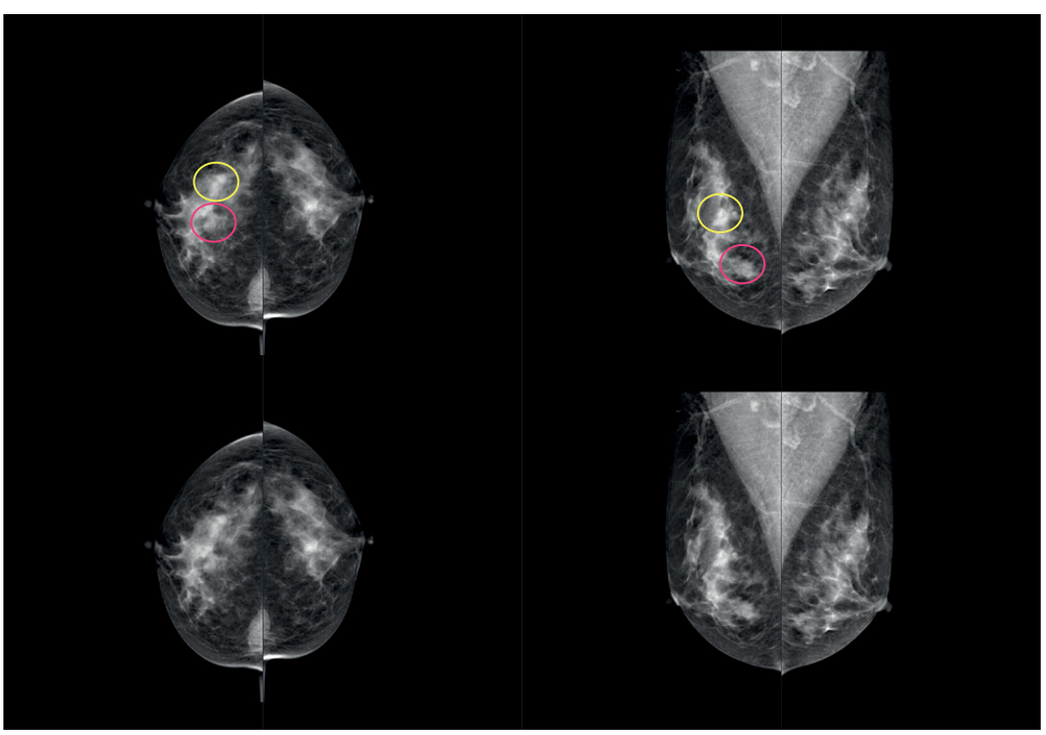
CASE 1 Typical mass(+calc) cancer - irregular spiculated mass in RUC, linearly distributed calc in RUI-RUC



CASE 2 Hard cancer case (missed by a radiologist) - focal asymmetry in LLC mid portion, (rim calc in RUI)

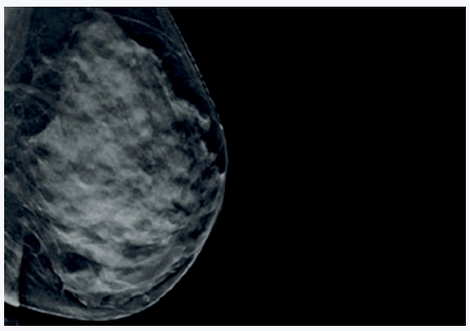


CASE 3 Hard cancer case - Obscured mass + grouped microcalc in RUI posterior portion



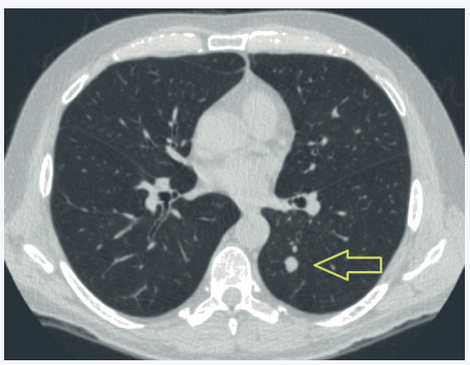
CASE 4 Typical benign mass - A circumscribed oval mass in RLI (pink) and a partially obscured mass in RUO (yellow)

OTHER RESEARCH IN RADIOLOGY



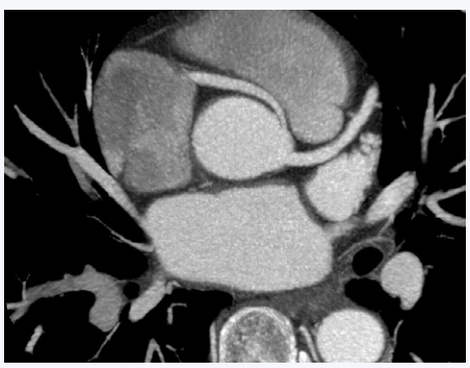
DIGITAL BREAST TOMOSYNTHESIS

DBT has been demonstrated by various large-scale studies to be superior to mammography in term of breast cancer screening performance. We are using our experience in mammography research to develop a highly accurate diagnostic algorithm for breast cancer detection in DBT.



CHEST COMPUTED TOMOGRAPHY

Lung cancer screening by low dose chest CT has been demonstrated to have survival benefit. Starting with accurate detection of lung nodules in chest CT, we plan to develop an imaging biomarker that accurately predicts malignancy of the detected nodules. Through the use of such imaging biomarker, not only will unnecessary invasive biopsy procedures may be avoided, but it may also be used to diagnose lung cancer at an earlier stage.



CORONARY COMPUTED TOMOGRAPHY ANGIOGRAPHY

Coronary heart disease is one of the most critical health issues throughout the world. Highly accurate prediction of major coronary events by coronary plaques in stable angina and/or high risk asymptomatic patients is being pursued. This would enable appropriate selection of high risk patients to receive early revascularization, as well as avoid unnecessary revascularizations in patients who would not benefit from aggressive treatment.

LUNIT INSIGHT FOR CHEST RADIOGRAPHY

Multi-stage deep disassembling networks for generating bone-only and tissue-only images from a chest radiography

PURPOSE

In order to disassemble a chest radiography (CR) into bone-only and tissue-only images to increase interpretability of CR, we developed a deep disassembling network for CR (DDNC) which is a cascaded multi-stage convolutional neural network. We evaluated the performance of DDNC by comparing ground truth bone-only and tissue-only images with our network produced images using structural similarity (SSIM).

MATERIALS & METHODS

Initially, we collected a total of 617 cases of bone-only and tissue-only CRs which was produced by dual energy subtraction technique. To purify the dataset, we manually excluded 100 cases which quality of images are poor, presenting severe motion artifact or loss of information due to the application of excessive post-processing when producing images. Furthermore, we refined the remaining cases using guided filter and non-local means filter to remove noises. Among delicately collected the 517 cases, we randomly divided 467 cases as train dataset and the rest 50 cases as validation dataset. We designed a novel two-stage deep convolutional network where the first-stage is designed for observing context of a CR and the second-stage is for producing bone-only and tissue-only images given the first-stage output. The network is constructed with residual architecture, 40 convolutions for the first-stage and 14 convolutions for the second-stage. We quantitatively measured the performance of our network using SSIM which measure the structure difference between a given ground truth image and our network produced image.

RESULTS

In validation dataset, the measured SSIM comparing ground truth tissue-only image and our network produced result was 0.9678. When we limit the region of interest (ROI) as lung area, which area is clinically important, the measured SSIM was 0.9835. In the case of bone-only image, it was 0.9877 and 0.9870 when we limit ROIs as whole image and lung area, respectively.

CONCLUSION

Deep learning based automatic disassembling network for producing bone-only and tissue-only images from a CR is demonstrated and the performance of the network is validated by SSIM proving its performance.

CLINICAL RELEVANCE STATEMENT

Conventional method for obtaining bone-only and tissue-only images of a CR requires a specialized hardware device for dual-energy subtraction technique while DDCN allows obtaining them from any CRs.

LUNIT INSIGHT FOR CHEST RADIOGRAPHY

Development and Validation of a Deep Learning-Based Automatic Detection Algorithm for Active Pulmonary Tuberculosis on Chest Radiographs

PURPOSE

To develop and validate a deep learning-based automatic detection (DLAD) algorithm for active pulmonary tuberculosis (TB) on chest radiographs (CRs).

MATERIALS & METHODS

For the development of DLAD, 54,221 normal CRs and 6,768 CRs with active pulmonary TB were retrospectively collected from a single institution and labeled by 13 board-certified radiologists. DLAD was developed with a 27-layer deep convolutional neural network, and its performance was validated using 6 external validation datasets (4 datasets from 4 institutions and 2 datasets from the US National Library of Medicine). Finally, to compare the performances of DLAD and physicians, an observer performance test was conducted by 15 physicians (5 non-radiology physicians, 5 board-certified radiologists, and 5 thoracic radiologists) using one of the external validation datasets. Diagnostic performance was measured using area under the receiver operating characteristic (ROC) curves for image-wise classification and with area under the alternative free-response ROC curves for lesion-wise localization. Sensitivities and specificities of DLAD were calculated using two cutoffs [high sensitivity (98%) and high specificity (98%)] obtained from the results of in-house validation.

RESULTS

DLAD demonstrated an image-wise classification performance of 0.977-1.000 and localization performance of 0.973-1.000 in the 6 external validation datasets. Sensitivities and specificities for image-wise classification were 94.3-100% and 91.1-100% using the high sensitivity cutoff and 84.1-99.0% and 99.1-100% using the high specificity cutoff. DLAD showed significantly higher performance in both classification (0.993 vs. 0.746-0.971 according to physician groups, all Ps <0.05) and localization (0.993 vs. 0.664-0.925 according to physician groups, all Ps <0.05) compared to physicians.

CONCLUSION

DLAD showed excellent and consistent performance in the detection of active pulmonary TB on CRs, outperforming physicians.

CLINICAL RELEVANCE STATEMENT

DLAD can classify CRs with active pulmonary TB and localize lesions at an expert's level, and thus may play a key role in the diagnosis and screening of active pulmonary TB.

LUNIT INSIGHT FOR CHEST RADIOGRAPHY

Deep Learning-Based Automatic Detection Algorithm for Detecting Major Thoracic Abnormalities on Chest Radiography

PURPOSE

In order to detect major thoracic abnormalities including nodule/mass, tuberculosis, pneumonia and pneumothorax on chest radiography, we developed deep learning based automatic detection (DLAD) algorithm, and evaluated its diagnostic performance and detection performance with large-scale chest radiographs (CRs) data.

MATERIALS & METHODS

We collected a total of 92,532 CRs comprised of 35,641 major thoracic abnormal cases (M:F=21,053:14,558; mean age=56), which includes 13,925 nodule/mass cases, 6,798 tuberculosis cases, 6,903 pneumonia cases and 8,015 pneumothorax cases, and 54,221 normal cases (M:F=24,592:29.629; mean age=50). The whole set was randomly split into a training set (53,393 normal and 30,679 abnormal CRs), a validation set (300 normal and 450 abnormal CRs) and a test set (300 normal and 450 abnormal CRs). We designed a deep convolutional neural network with 27 layers and 12 residual connections, and trained this network with 71,376 label-only CRs and 12,696 annotation CRs which 15 thoracic radiologists manually tagged the lesion locations. We quantitatively verified the performances of DLAD by analyzing the receiver-operating characteristics (ROC) curve for classification performance and jackknife alternative free-response receiver-operating characteristics (JAFROC) for detection performance. All CRs in the validation set and the test set were annotated by 5 out of 15 thoracic radiologists for detection performance, and the final decision on the location of each abnormal lesion was made by majority.

RESULTS

In the test set, DLAD showed an area under the ROC curve (AUC) of 0.9811 and an area under the JAFROC of 0.9656. The AUC and JAFROC of each disease compared to normal CRs was 0.9674, 0.9494 for nodule/mass, 0.9902, 0.9742 for tuberculosis, 0.9854, 0.974 for pneumonia and 0.9937,0.98 for pneumothorax, respectively.

CONCLUSION

Deep learning based automatic detection algorithm shows cutting-edge performance in differentiating normal from abnormal CRs, but also detects the location of lesions.

CLINICAL RELEVANCE STATEMENT

As a second reader, DLAD is expected to augment radiologists read chest radiographs with high accuracy.

LUNIT INSIGHT FOR CHEST RADIOGRAPHY

Performance Validation of a Deep Learning-Based Automatic Detection Algorithm for Major Thoracic Abnormalities on Chest Radiographs

PURPOSE

To evaluate the performance of a deep learning-based automatic detection (DLAD) algorithm for major thoracic abnormalities including malignant pulmonary nodules/masses, tuberculosis, pneumonia, and pneumothorax on chest radiographs (CRs) in comparison with physicians.

MATERIALS & METHODS

DLAD was developed using a 27-layer deep convolutional neural network. External validation of its diagnostic performance was conducted using 2 separate datasets from 2 institutions (normal: abnormal = 97:103 and 100:84). For comparison with physicians, an observer performance test was conducted using 1 of the datasets including 15 physicians (5 non-radiology physicians, 5 board-certified radiologists, 5 thoracic radiologists). All physicians reviewed each CR twice, without and with DLAD, and determined the presence of clinically significant thoracic abnormalities on a 5-point scale. Performance measurements were done using area under the receiver operating characteristic (ROC) curves for image-wise classification and area under the alternative free-response ROC curves for lesion-wise localization.

RESULTS

Image-wise classification performances of DLAD for abnormal CRs were 0.983 and 0.993 and lesion-wise localization performances were 0.974 and 0.985 on the two external validation datasets. Without DLAD, average classification performances of non-radiology physicians, board-certified radiologists, and thoracic radiologists were 0.813, 0.896, and 0.932, and average localization performances were 0.781, 0.870, and 0.907, respectively. DLAD demonstrated significantly higher performance in image-wise classification and lesion-wise localization compared with all reader groups (all Ps <0.05). With DLAD, physicians' diagnostic performances were significantly improved in classification (0.904, 0.939, 0.958; all Ps <0.05) and localization (0.873, 0.919, 0.938; all Ps <0.05) in all reader groups.

CONCLUSION

DLAD showed excellent and consistent performance in the detection of active pulmonary TB on CRs, outperforming physicians.

CLINICAL RELEVANCE STATEMENT

Our DLAD algorithm can accurately classify abnormal CRs and localize abnormal findings, and has the potential to improve diagnostic accuracy, patients' safety, and clinical workflow efficacy.

LUNIT INSIGHT FOR MAMMOGRAPHY

Data-driven Imaging Biomarker for Breast Cancer Screening in Mammography

PURPOSE

Previously, we demonstrated data-driven imaging biomarker in mammography (DIB-MMG; an imaging biomarker that is derived from large-scale mammography data by using deep learning technology) for detection of malignant lesions. Now, we assess the feasibility of DIB-MMG as a diagnosis-support-tool for radiologists.

MATERIALS & METHODS

Total 96,191 exams of 4-view digital mammograms were retrospectively collected from two institutions. All cancer exams were proven by biopsy. Benign exams were proven by biopsy or at least 1 year of follow-up mammography, and normal exams were proven by at least 1 year of follow-up mammography. 90,637 exams of training data (16,086 cancer, 31,237 benign, and 43,314 normal exams) and 5,554 exams of test data (1,692 cancer, 2,780 benign, 1,082 normal cases) were used for developing the DIB-MMG. Sensitivity, specificity, and AUC of the final DIB-MMG on the test data were 82.6%, 93.3%, and 0.94, respectively. Total 120 exams of mammograms (38 cancer and 82 non-cancer exams) were independently collected for reader study, and five radiologists (two radiologists with 1 year of fellowship training and three residents) participated. For each exam, readers first read the exam without the help of DIB-MMG and Task-1) annotate the most suspicious lesion with DMIST 7-pt scores and Task-2) decide recall or not per breast. After reading of each exam, readers modify their decision based on the heat-map of DIB-MMG which denotes the likelihood of malignancy.

RESULTS

Per-breast standalone performance of DIB-MMG for 120 exams was 0.942 of AUC in Task-1, and 89.7% of sensitivity, 89.6% of specificity in Task-2. Average performance of five radiologists without DIB-MMG was 0.807 of AUC in Task-1, and 70.8% of sensitivity, 86.2% of specificity in Task-2. With DIB-MMG, the average performance was improved to 0.879 of AUC (p=0.024) in Task-1, and 79.5% of sensitivity, 86.5% of specificity in Task-2.

CONCLUSION

This retrospective reader study showed the potential of DIB-MMG as a diagnosis-support-tool for radiologists in breast cancer screening. Further clinical validation with prospective study is needed.

CLINICAL RELEVANCE / APPLICATION

DIB-MMG is purely based on data-driven features from a large-scale mammography data instead of manually designed features of conventional computer-aided detection (CAD) algorithms. With further clinical validation, DIB-MMG can be practically used as a diagnosis-support-tool for radiologists in breast cancer screening.

LUNIT INSIGHT FOR DIGITAL BREAST TOMOSYNTHESIS

Data-driven Imaging Biomarker for Breast Cancer Screening in Digital Breast Tomosynthesis

PURPOSE

To assess feasibility of a data-driven imaging biomarker in digital breast tomosynthesis (DIB-DBT) using the deep learning technology and evaluate its potential for detection of breast cancer.

MATERIALS & METHODS

We retrospectively collected 49,577 exams of 4-view digital mammograms (MMG) and 1,196 exams of 4-view digital breast tomosynthesis images (DBT) from a single institution. We also collected 41 (10 cancer, 16 benign, 15 normal) exams of 4-view DBT retrospectively from another institution for external validation. 49,577 exams of MMG consists of 47,719 (5,599 cancer, 17,971 benign, and 24,149 normal) and independent 1,858 (619 cancer, 620 benign, 619 normal) exams of training and validation data, respectively. 1,196 exams of DBT consists of 996 (822 cancer, 40 benign, 134 normal) and independent 200 (120 cancer, 30 benign, 50 normal) exams of training and validation data, respectively. Previously, we assessed the feasibility of DIB-MMG as a screening tool for breast cancer detection in mammograms through external validation and pilot reader study. Thus, we exploit DIBMMG for developing DIB-DBT in this study. Training of DIB-DBT consists of two stages – semi-supervised pretraining with partially-annotated large-scale MMG followed by fully-supervised fine-tuning with fully-annotated small-scale DBT. Residual network for image recognition is used as a baseline model. Diagnostic accuracy of DIB-DBT was assessed using receiver operating characteristic analysis.

RESULTS

Area under the curve (AUC) on the internal validation dataset of DIB-DBT with and without the pre-training stage of DIB-MMG was 0.9227 and 0.9081, respectively. AUC of the external validation dataset of DIB-DBT with and without the pre-training stage of DIB-MMG was 0.9232 and 0.9710, respectively.

CONCLUSION

This study showed the feasibility of DIB-DBT as a screening tool for breast cancer detection in DBT. This research also showed the potential of DIB-MMG as a base model for DIB-DBT. Further clinical validation of DIB-DBT is needed for using it as a reliable screening tool for breast cancer screening.

CLINICAL RELEVANCE / APPLICATION

With further clinical validation, DIB-DBT could be practically used as a second-reader to help radiologists detecting and diagnosing breast cancer in DBT efficiently.

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