

AI Models for Chest Radiograph Analysis: Internal Clinical Trial vs. Gold Standards

Mr. Pritam Dhalla¹, Mr. Soham Pal^{*2}, Mr. Amar Saish³

¹Director of Larkai Healthcare Pvt. Ltd & Gurugram, India

²Innovation Associate of Larkai Healthcare Pvt. Ltd & Gurugram, India

³AI Engineer of Larkai Healthcare Pvt. Ltd & Gurugram, India

ABSTRACT

Our vision is to develop an AI-based software which is capable of analyzing frontal PA chest X-rays for disease diagnosis, detection, and prediction through the analysis of several different X-ray manifestations and findings which are inter-correlated to arrive to a final result. We utilize state-of-the-art AI, thereby facilitating in empowering of the world through our med-tech ecosystem. It is being developed with the intention of enhanced cardiopulmonary care, bridging the gaps in healthcare, by giving conclusive and comprehensive diagnosis at lower costs and reducing the number of unnecessary diagnostic tests which, often, serve as the main cause of the delay between diagnosis and treatment.

Why X-rays? X-rays have been chosen as the input because it is Non-invasive mode of diagnostic test, affordable, accessible and has much lesser radiation exposure compared to other imaging methods of CT, MRI, PET.

KEYWORDS: x-ray, chest radiography, deep learning, segmentation, computer vision, cardiopulmonary care

PURPOSE: The purpose of conducting an in-house clinical trial to assess deep learning models for chest radiograph elucidation against established gold standards, employing a comparative analysis approach against established gold standards, employing a comparative analysis approach

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I. INTRODUCTION

Cardiomegaly, mass detection, and pneumonia are three diseases with significant global importance due to their prevalence, impact on public health, and the number of lives affected. Efforts to improve prevention, early detection, and treatment of these conditions are essential for reducing their burden on individuals and healthcare systems worldwide. Cardiomegaly, also known as an enlarged heart, is a condition characterized by an increase in the size of the heart chambers. It can be a result of various underlying conditions such as hypertension, coronary artery disease, or heart valve disorders. Cardiomegaly is a significant global health concern due to its association with cardiovascular diseases, which are among the leading causes of morbidity and mortality worldwide. The prevalence of cardiomegaly varies depending on the underlying cause and population demographics. It is more common in older adults and

individuals with underlying heart conditions. In developed countries, the prevalence is estimated to be around 1-2%. Cardiomegaly affects millions of people worldwide, leading to complications such as heart failure, arrhythmias, and increased risk of sudden cardiac death. It imposes a significant burden on healthcare systems and can drastically impact the quality of life of affected individuals^[1].

Mass detection refers to the identification and characterization of abnormal growths or masses in the body, which may be benign or malignant tumors. Early detection is crucial for timely intervention and improved treatment outcomes. Mass detection plays a critical role in cancer diagnosis and management, as early detection enables timely treatment and improves survival rates. The prevalence of masses varies depending on the type of tumor and population demographics. Cancer incidence rates have been steadily increasing globally, with certain types of

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cancer more prevalent in specific regions or populations. Mass detection affects millions of individuals worldwide, while cancer continues to be the world's greatest cause of death. Beyond the physical toll, cancer diagnosis can also have profound psychological and socio-economic impacts on patients and their families [2].

Pneumonia is an inflammatory condition of the lungs, primarily caused by bacterial, viral, or fungal infections. It can range from mild to severe and is a major global cause of morbidity and mortality, especially for people that are already vulnerable. Pneumonia is a significant global health concern, particularly in developing countries, where access to healthcare and vaccination coverage may be limited, this affects people of all ages but is most prevalent in young children, the elderly, and individuals with weakened immune systems. It is estimated that pneumonia accounts for over 2 million deaths annually worldwide. Pneumonia disproportionately affects children below the age of five in developing countries, where it is a leading cause of childhood mortality. However, it also poses a significant health threat to older adults and individuals with underlying health conditions, contributing to hospitalizations and healthcare costs globally [3].

In the domain of radiology, deep learning models offer the potential to augment radiologists. Diagnostic accuracy and efficiency. Chest radiography is one of the most performed imaging studies, playing a crucial role in the diagnosis and management of respiratory and cardiac conditions. Evaluating deep learning models against gold standard interpretations is essential to determine their clinical validity and establish their role in routine clinical practice. This study outlines the design and implementation of an in-house clinical trial to rigorously evaluate deep learning models for chest radiograph interpretation.

We have taken Chest Xray as our input for analysis software because,

Non-invasive: X-rays provide valuable diagnostic information without the need for invasive procedures, reducing patient discomfort and risk of complications.

Affordable: Chest X-rays are relatively inexpensive compared to other imaging modalities such as CT (computed tomography) or MRI (magnetic resonance imaging), making them more accessible to a broader population.

Accessibility: X-ray facilities are widely available in hospitals, clinics, and even some primary care settings, ensuring convenient access to diagnostic imaging for patients.

Low Radiation Exposure: While X-rays do involve exposure to ionizing radiation, the dose used in chest X-rays is typically much lower than that of CT scans. This reduces the potential risk of radiation-related harm to patients, especially when repeated imaging is necessary.

MODALITY	DOSE
CXR	0.02 mSv
Skull X Ray	0.07 mSv
Abdomen X ray	1 mSv
Mammography	0.5 – 0.7 mSv
CT head	2 mSv
CT chest	5 mSv
CT abdomen	10mSv
PET	10-12 mSv
Barium meal follow through /enema	7-8 mSv
IVP	2-3mSv

II. MATERIALS AND METHODS

A. Datasets

Open-access datasets of chest X-ray images was taken can be found in various repositories and databases. Which included data set from CXR14, Radiopaedia, sage journals , research gate , radiology master class , BMJ, Semantic scholar, Shutterstock, wikidoc, SringerLink etc^[4].

For our research project, we gathered a diverse range of chest X-ray image datasets from several reputable repositories and databases. One of the primary sources we utilized was the CXR14 dataset.

In addition to CXR14, we accessed publicly available chest X-ray images from various scholarly platforms, including Radiopaedia, SAGE Journals, ResearchGate, Radiology Masterclass, BMJ (British Medical Journal), Semantic Scholar, Wikidoc, and SpringerLink. These platforms provided access to a wealth of annotated and unannotated chest X-ray images, enhancing the breadth and depth of our dataset.

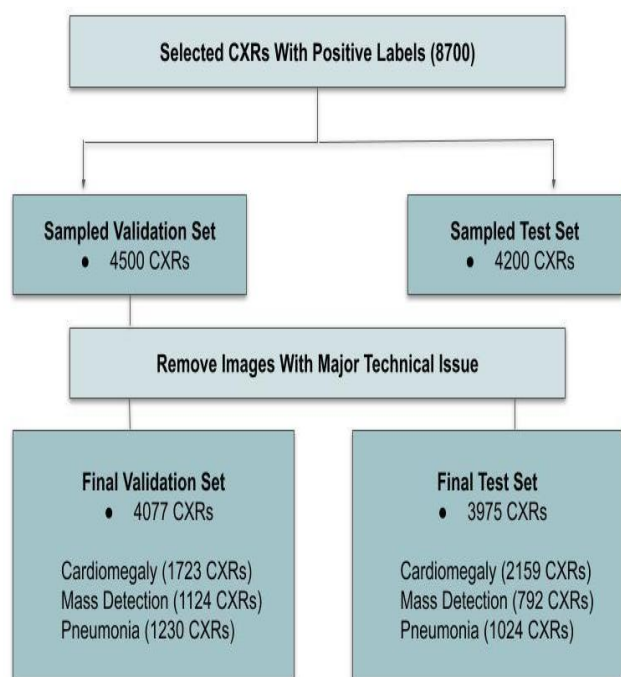
Furthermore, to ensure a well-rounded dataset, we incorporated images from commercial platforms such as Shutterstock. While these images may require licensing or purchasing, they provided valuable diversity in terms of patient demographics, imaging techniques, and pathology presentations.

By leveraging datasets from these diverse sources, we aimed to create a comprehensive and representative collection of chest X-ray images. This approach not only enriched our analysis but also enhanced the robustness and generalizability of our research findings, enabling us to address a wide range of research questions and challenges in the field of medical imaging.

B. Validation and Test Set Image Selection

Validation and Test Set Image Selection To provide a sufficient number of diverse and high-quality labelled images with findings positive cardiomegaly, mass detection and pneumonia we selected approximately 8700 images from open sources were taken.

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The dataset contains chest X-rays that have been labelled with positive labels for certain findings. Specifically, shows that the dataset contains 8,700 chest X-rays in total. These have been split into a validation set of 4,500 images and a test set of 4,200 images. Some images with major technical issues have been removed, leaving 4,077 images in the final validation set and 3,975 images in the final test set. The labels included in the dataset are Cardiomegaly, this is a condition in which the heart is enlarged. There are 1,723 chest X-rays in the dataset that have been labelled with this finding in the validation set, and 2,159 in the test set. Mass detection, this refers to the identification of a mass in the lung tissue. There are 1,124 chest X-rays in the validation set and 792 in the test set that have been labelled with this finding. Pneumonia; this is an infection of the lungs. There are 1,230 chest X-rays in the validation set and 1,024 in the test set that have been labelled with this finding.

C. Reference Standard Image Annotation

Three chest radiography findings—cardiomegaly, mass annotation, and pneumonia—were the targets of our search. Cardiomegaly refers to heart enlargement; 50% or more of the transverse width of the chest represents the transverse width of the cardiac outline on a computed tomography or chest radiograph projected posteriorly and anteriorly. (increased cardiothoracic ratio)^[5]. A nodule was defined as less than 3 cm and a mass as 3 cm or more for the purpose of mass detection. Each of these observations was labeled at the picture level as either present or absent. Pneumonia causes the lungs to fill with fluid^[6].

D. Model Development

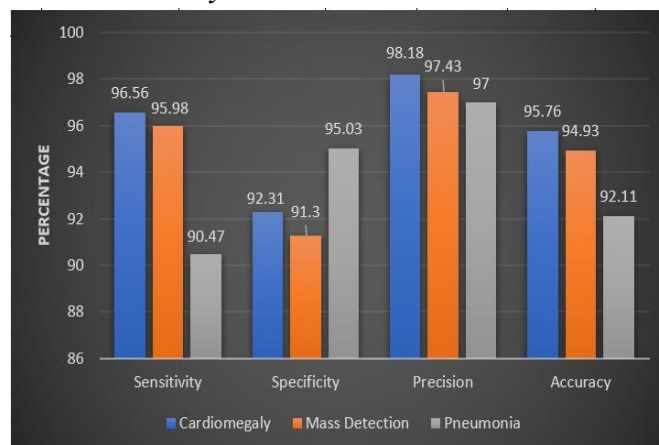
Our software used to detect multiple diseases from cxr. The different diseases here is a mixture of multiple models, each

disease here has multiple deep learning and computer vision models. Deep learning models used are hybridnet, resnet, Unet, and also neural network models developed. Computer vision models is yolov8 detection, yolov8 classification and maskrcnn.

Each of these models likely serves a specific purpose within your software pipeline. For instance, ResNet and HybridNet may be used for image classification tasks, while UNet could be employed for segmentation tasks. YOLOv8 detection and classification models are suited for object detection and classification tasks, and Mask R-CNN is commonly used for instance segmentation.

By leveraging this mix of models, your software can potentially provide robust and comprehensive disease detection capabilities from chest X-ray images, covering a wide range of pathologies and abnormalities^[7]. It's important to carefully integrate and fine-tune these models to ensure optimal performance and accuracy in disease detection^[8]. Additionally, continuous evaluation and refinement of the models based on real-world data and feedback are crucial for enhancing the software's effectiveness in clinical settings.

E. Statistical Analysis

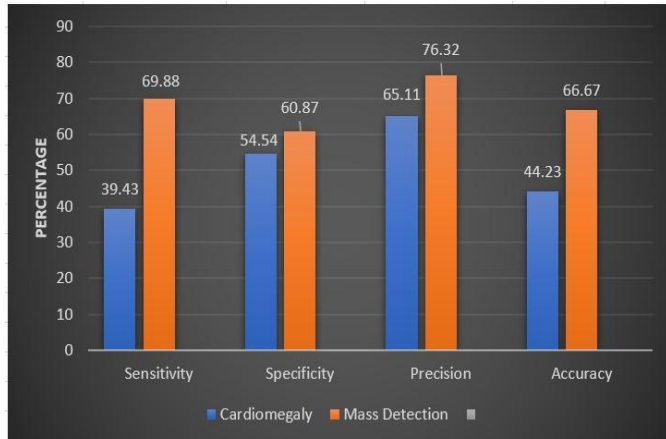


Precision value of 1 shows perfection, while that of 0 shows no perfection. A value closer to 1 is a near perfect value, while one closer to 0 is undesired. Cardiomegaly showed a sensitivity, specificity, precision, and accuracy of 96.56%, 92.31%, 0.98, and 95.76% respectively. Mass Detection showed a sensitivity, specificity, precision, and accuracy of 95.98%, 91.3%, 0.97, and 94.93% respectively. Pneumonia showed a sensitivity, specificity, precision, and accuracy of 90.47%, 95.03%, 0.97, and 92.11% respectively.

Possible reasons behind the reductions in values of accuracy, and sensitivity of pneumonia for Bluetail are the haziness of the images, possible confusion of the model between pulmonary artery and fluid ie. inability to differentiate between fluid whitening and tissue whitening and vasculature whitening.

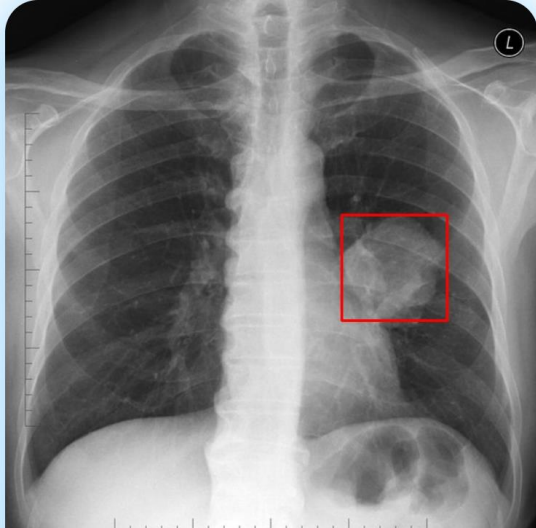
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F. Competitive Analysis



In the realm of medical software, an esteemed platform excels in detecting masses and cardiomegaly, yet its diagnostic capacity regarding pneumonia remains absent. Instead, it identifies opacity and consolidation, which encompass a spectrum of pathologies, including pneumonia. The evaluation of cardiomegaly yields a sensitivity of 39.43% and specificity of 54.54%, translating to a precision of 0.65 and an accuracy of 44.23%. Mass detection, on the other hand, demonstrates a sensitivity of 69.88%, a specificity of 60.87%, with a precision of 0.76 and an accuracy of 66.67%.

RESULTS



No Cardiomegaly 42%
Mass detected
PNEUMONIA is not detected

(A) Image and text outputs report generated by BlueTAIL.



Nodule observed in left mid and lower zones.
No blunting in CP angles is seen.
No significant findings observed in the heart.
Trachea is centrally located.
Bony thorax appears unremarkable.
Both hila appear normal.

(B) Image and text outputs report generated by "COMPANY A".

The software application of Company A is unable to differentiate between nodule and mass, where masses are >3cm, and nodules are smaller. Annotation by BlueTAIL is precise and distinctly visible, while that of Company A is not distinctly visible, and covers much extra areas as well.

This is an example of the disease detection abilities of the 2 model with respect to cardiomegaly, mass, and pneumonia.

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