

LDCT for Screening of Lung Nodules: 7 Year Experiences from a Tertiary Hospital in India

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ABSTRACT

Introduction: Lung cancer is one of the leading causes of cancer related deaths. Various studies conducted across the world regarding Low Dose Computed Tomography (LDCT) screening have demonstrated early detection of lung nodules and reduced mortality. Our study aims to report the findings of LDCT screening for lung nodules over seven years in a tertiary hospital in central Kerala.

Methods: Subjects who underwent LDCT Chest as part of wellness health check-up from January 2017 to December 2023, were evaluated in the study. Images were reviewed for the presence of nodules/ mass and categorized as per Lung-RADS criteria. A positive LDCT screen was defined as a presence of a mass lesion or at least one non-calcified nodule of ≥ 6 mm in diameter.

Results: LDCT chest scans of 1500 subjects were included and evaluated in the study. Total screen positivity in the present study included total 96 subjects out of 1500 (3 subjects with mass + 64 subjects with solitary non-calcified nodules + 29 subjects with multiple non-calcified nodules) which accounted for a total positive screen of 6.4%. Subjects were also classified as per Lung-RADS Categories: Category 1 - 84.9%, Category 2 - 8.7%, Category 3 - 3.9%, Category 4 - 2.5%. Even though, most of the subjects with positive screen were lost to follow up; among those who underwent follow-up scans, nodules remained relatively stable in majority. Only two biopsy positive lung cancer was found among the total 1500 subjects screened (0.13%).

Conclusion: LDCT screening has been highly sensitive in the detection of lung nodules. But, in a tuberculosis endemic country like India, results may not be specific for lung cancer with many false positive results. Hence, further detailed study among high-risk subjects with proper follow up must be done for developing necessary guidelines for the use of LDCT screening in India.

Keywords: lung cancer, lung nodule screening, Low Dose Computed Tomography (LDCT).

INTRODUCTION

Lung cancer is one of the leading causes of cancer related deaths globally and in India. In India, Lung cancer is responsible for 5.9% of all cancers and 8.1% of all cancer related deaths¹. Smoking is one of the important risk factors in the development of lung cancer and it is very much prevalent in Indian population; hence, at high risk for this malignancy. Moreover, most lung cancers were diagnosed at an advanced stage and led to increased mortality.

Screening programmes are important for early diagnosis and for reducing the mortality rate of lung cancer. Various trials across countries have found that chest x-ray screening did not show any significant reduction in lung cancer mortality. Lung cancer screening using low-dose computed tomography (LDCT) has been found to be effective and highly sensitive imaging modality in detecting lung cancer at a smaller size and earlier stage. LDCT screening together with recent advances in treatment options have resulted in improved 5yr survival rates in early-stage lung cancer patients (60-80%)². The National Lung Screening Trial (NLST), one of the world's largest multicenter randomized CT screening trials (USA, 2011) using LDCT in USA showed 20% reduction in lung cancer mortality³.

Lung-RADS (Lung Imaging Reporting and Data System) has been proposed as a standard classification system to be used in LDCT screening for lung cancer. Basic understanding of Lung-RADS: Category 1 (negative) - no nodule/ nodule with calcification, Category 2 (benign) - solid nodule <6 mm, Category 3 (probably benign) - solid nodule \geq 6 to <8 mm, Category 4A (suspicious) - solid nodule \geq 8 to <15 mm, Category 4B (very suspicious) - solid nodule \geq 15 mm, Category 4X (very suspicious) - category 3 or 4 nodule with spiculation⁴.

Many studies have been conducted on LDCT screening for lung cancer among various populations. However, there exists scarcity of data in the Indian context. Our study aims to report the findings of lung nodule

screening using LDCT over seven years in a tertiary hospital in central Kerala (southernmost state in India).

METHODS

The study was conducted in the Department of Radiodiagnosis at Believer's Church Medical College Hospital (a tertiary care center in Thiruvalla, Kerala), after getting clearance from Institutional Research and Ethical committees.

Retrospective data of all the patients, who underwent non-contrast LDCT of the Chest as part of wellness general health packages from January 2017 to December 2023, were evaluated in the study.

All the CT scans were performed in a Philips Ingenuity 128 slice CT scanner from lung apex to base. All the CT images were acquired in low dose protocol. The technical parameters adopted in the acquisition of tomographic images include 100-kV tube voltage, 170 effective mAs, 0.75 s rotation time, slice thickness of 1 mm, pitch 1 and a field of view of 15 cm. The CT images were analyzed using Philips Workstation having IntelliSpaceTH Portal Operating system.

Images of all the subjects were analyzed by the radiologists for the presence of nodules or mass. A positive LDCT screen was defined as a presence of a mass lesion or at least one non-calcified nodule of \geq 6 mm in diameter. The largest nodule was categorized as per Lung-RADS criteria. Statistical analyses were done using IBM SPSS Statistics. Follow-up CT scans of the subjects with positive LDCT screen and biopsy reports, if any were also assessed.

RESULT

LDCT chest scans of 1500 subjects were included and evaluated in the study. Among 1500 subjects, 968 were males (64.5%) and 532 were females (35.5%). Youngest subject was 29 years and eldest was 85 years old. The mean age of the study group was 60 years. Majority of the study subjects were more than 60 years old (60.4%) and 38.5 % were in 40-60 age group and 1.1 % below 40 years.

Nodules ≥ 6 mm were assessed for screen positivity. Among the 1500 subjects, nodules ≥ 6 mm were found in 125 subjects (8.3%). Nodules can be categorized into solitary / multiple and calcified / non-calcified nodules. Among the 125 subjects with nodules, 88 were solitary (70.4%), (5.9% of total 1500 subjects) and 37 had multiple nodules (29.6%), (2.4% of total 1500 subjects). Also, among the 125 subjects with nodules, 32 had only calcified nodules (25.6%), (2.1% of total 1500 subjects) and 93 subjects had at least one non-calcified nodule (74.4%), (6.2% of total 1500 subjects) [Table 1].

Among those with solitary nodules ≥ 6 mm (88), 69 (78.4%) were males and rest 19 (21.6%) were females. Majority of them 58 (65.9%) were more than 60 yrs, 29 (33%) were between 40-60 yrs and rest 1 (1.1%) was less than 40 years. Among those with solitary nodules (88), 64 (72.7%) were solitary non-calcified and rest 24 (27.3%) were calcified. 49 (76.6%) out of the 64 subjects with solitary non-calcified nodules were males. 39 (60.9 %) of 64 subjects with solitary non-calcified nodules were more than 60 yrs, 24 (37.5%) were between 40-60 yrs and one subject (1.6%) was less than 40 years.

Among those with multiple nodules ≥ 6 mm (37), 27 (73%) were males and rest 10 (27%) were females. Majority of them 26 (70.3%) were more than 60 yrs and rest 11 (29.7%) were between 40-60 yrs. Among those with multiple nodules (37), 29 (78.4%) were having at least one non-calcified nodule and rest 8 (21.6%) were all calcified. 20 (69%) of 29 subjects with multiple non-calcified nodules were males. 19 (65.5 %) of 29 subjects with multiple non-calcified nodules were more than 60 yrs and rest 10 (34.5%) were between 40-60 yrs.

Among 1500 subjects, 3 subjects had mass lesions (0.2%); all were above 60 years, 2 males and 1 female [Table 2,3].

Total screen positivity included those with lung mass like lesions and those with solitary/ multiple non-calcified lung nodules of ≥ 6 mm; ie in the present study, total 96 subjects out of 1500 subjects were positive (3

mass like lesions + 64 solitary non-calcified nodules + 29 multiple non-calcified nodules) which accounts for a total positive screen of 6.4%. Among the total positive screen (96), 71 (74%) of subjects were males and 25 (26%) were females. 61 (63.6 %) of subjects were more than 60 yrs, 34 (35.4%) were between 40-60 yrs and rest 1(1%) less than 40 years [Table 1].

Subjects were also classified as per Lung-RADS Categories: Category 1 - 84.9% (1273 subjects = 1165 with no nodules or mass and 108 nodules with calcification), Category 2 - 8.7% (131 subjects), Category 3 - 3.9% (58 subjects), Category 4 - 2.5% (38 subjects). Among 38 Category 4 subjects; 23 were 4A, 5 were 4B, 10 (including 3 masses) were 4X [Table 4].

Also, among 1500 subjects, nodules < 6 mm were found in 207 subjects. Among them, 76 were calcified, 131 non-calcified and 117 solitary, 90 multiple. 63 were solitary non-calcified, 68 multiple non-calcified, 54 solitary calcified, 22 multiples calcified [Table 1].

Other incidental findings obtained in the study include: Presence of interstitial lung disease (ILD) in 1.3%, bronchiectasis in 9.7%, emphysema in 7.3%, lung cysts in 5.2%, lung infection in 5.7%, mediastinal mass in 0.2%, mediastinal lymphadenopathy in 0.7% subjects.

Among the 96 subjects with positive screen, only two subjects (2/1500 = 0.13%) turned out to be biopsy positive for lung malignancy (one subject presented as lung mass and other subject had multiple nodules, largest measured 16 mm in initial CT which on follow-up showed interval increase in size and later biopsy positive). Majority of subjects (72) with positive screen results were lost to follow-up. In rest of subjects with positive screen (22), nodules remained relatively stable on follow-up (17) or got resolved on follow-up (4) or turned biopsy negative (1). Among the three subjects with lung mass like lesions, one was lost to follow-up, one was biopsy positive and other was biopsy negative for malignancy.

Table 1: Showing distribution of subjects according to Lung-RADS classification

Lung RADS	Types	Number	Total
1	No Nodule	1165 (77.7%)	1273 (84.9%)
	Nodule with Calcification	108 (7.2%)	
2	Nodule <6 mm	131 (8.7%)	131 (8.7%)
3	>=6 to <8 mm	58 (3.9%)	58 (3.9%)
4	4A - >=8 to <15 mm	23 (1.5%)	38 (2.5%)
	4B - >=15mm	5 (0.33%)	
	4X - 3 or 4 with spiculation	10 (0.66%)	

Table 2: showing distribution of subjects with nodules <6mm, nodules >=6mm, mass>3cm with respect to number of lesions and presence of calcification.

		Nodule < 6mm		Nodule >=6mm - 3cm		Mass > 3 cm	
Solitary	Calcified	117 (7.8%)	54 (3.6%)	88 (5.9%)	24 (1.6%)	3 (0.2%)	0
	Non-calcified		63 (4.2%)		64 (4.3%)		3 (0.2%)
Multiple	Calcified	90 (6%)	22 (1.5%)	37 (2.4%)	8 (0.5%)	0	0
	Non-calcified		68 (4.5%)		29 (1.9%)		0
Total		207 (13.8%)		125 (8.3%)		3 (0.2%)	

Table 3: showing distribution of subjects with nodules >= 6mm and mass with respect to age, number of lesions and presence of calcification.

Age group	Solitary		Multiple		Mass
	Calcified	Non-calcified	Calcified	Non-calcified	
20 - 40 yrs	0	1	0	0	0
41 - 60 yrs	5	24	1	10	0
>60 yrs	19	39	7	19	3
Total	24	64	8	29	3

Table 4: showing distribution of subjects with nodules >= 6mm and mass with respect to sex, number of lesions and presence of calcification.

Sex	Solitary		Multiple		Mass
	Calcified	Non-calcified	Calcified	Non-calcified	
Male	20	49	7	20	2
Female	4	15	1	9	1
Total	24	64	8	29	3

DISCUSSION

Various studies were conducted across the world regarding LDCT screening in the assessment of lung nodules.

USA - The National Lung Screening Study (NLST), a multicentric study among 53454 subjects randomly assigned to LDCT/ chest x-ray. LDCT screen positivity rates were around 24.2% over all 3 rounds (A positive LDCT screen included a non-calcified nodule of at least 4 mm in diameter). 649 out of 1060 lung cancers in LDCT group were screen detected (2.4%)³.

Canada - LDCT screening demonstration project by the British Columbia Cancer agency among 561 subjects; abnormal screen (at least one non-calcified nodule) rate was

46% (259/561). 21 lung cancers were detected by screening (3.7%)⁵.

Brazil - Brazilian Lung Cancer Screening Trial (BRELT1) among 790 individuals, positive screen rate was 39.5% (nodules >4 mm) and 18.4% (nodules 6 mm or larger). Lung cancer was detected in 10 subjects (1.2%)⁶.

Italy - LDCT screening demonstration project in Lombardy enrolling 1035 volunteers; screen positivity was 4.4% (nodule >5 mm). Lung cancer yield was 1.1%⁷.

MILD (Multicentric Italian Lung Detection) trial among 4099 participants randomized into 3 groups; annual LDCT / biennial LDCT / control groups. Screen positivity (nodule 4.8 mm and above) was 15.3% and 13.7 % in

annual and biennial LDCT groups respectively at baseline. Lung cancer was detected by screening among 49 participants (29 annual 2.5% & 20 biennial 1.7%)⁸

Italgung Trial in Tuscany with a total of 3,206 subjects randomized into screening and control arms. Lung cancer was detected in 67 screening arm and 71 control arm subjects⁹.

France - LDCT screening trial randomized 621 enrolled subjects to LDCT (336) or CXR (285) arms. At least one non-calcified nodule was seen in 152 (45.2%) subjects in LDCT screen. Nodules < 5 mm, ≥ 5 to 10 mm and ≥ 10 mm seen in 71 (21.1%), 53 (15.8%) and 28 (8.3%) subjects respectively. Lung cancer was detected in 8 (2.4%) subjects in LDCT screen and in one subject (0.4%) in CXR screen².

Netherlands/ Belgium - Dutch-Belgian Lung Cancer Screening Trial (NELSON), a randomized trial, comparing LDCT screening with usual care and enrolled 15822 participants in LDCT screening and control arm in halves. Screen outcomes assessed based on volumetric measurements; for newly detected solid nodules, the volume categories of <50, 50–500 and >500 mm³ were classified as negative, indeterminate and positive. Study involved 4 rounds; baseline, 1, 3 and 5.5 years. At baseline, 19.2% of subjects had an indeterminate screen result and 1.6% a positive result. 255 screen-detected lung cancers were seen across the 4 rounds¹⁰.

United Kingdom - UK Lung Cancer Screening Trial (UKLS), a randomized pilot trial which included 4055 high risk consented subjects into screening arm and control arm. Out of 1994 subjects who underwent LDCT, overall screen positivity was 50.7%. Lung cancer detection rate from the screen was 2.1% (1.7% at baseline and 0.4% at 12 months follow-up CT)¹¹.

Germany - Lung Cancer Screening Intervention Trial (LUSI) in 2007 randomized 4052 participants from Heidelberg area into LDCT screening and control arms. Newly detected nodule of ≥ 5 mm considered positive screen. At baseline

scan, 22.2% had positive screen with cancer detection rate of 1.1%¹².

Korea - LDCT lung cancer screening launched in 1999 at Samsung medical center and screened 6406 individuals over 4 years and were categorized into three groups <5 mm, 5-10 mm, and >10 mm in diameter. 35% had at least one non-calcified nodule. 23 lung cancer cases were detected (detection rate 0.36 %) in baseline (11) / follow-up (12) studies¹³.

Taiwan - One year LDCT screening was done as part of yearly medical examinations in 2012 among 3339 individuals. Positive screen included the presence of any non-calcified nodule ≥ 4 mm. The positivity rate was 38.3%. 34 lung cancers were detected (cancer detection rate 1%)¹⁴. Another LDCT lung cancer screening study was done among relatives (1102 individuals) with family history of lung cancer involving six medical centers in Taiwan. Overall lung cancer detection rate was 7.7% (50 individuals)¹⁵.

Studies of LDCT screening in India are limited. A pilot, proof of concept study regarding LDCT screening was done in Maharashtra using retrospective data from 2016 to 2019 among 350 smokers. Lung nodules found in 93% (325 subjects) - Lung-RADS Category 1 - 36% (117), Category 2 - 41% (133), Category 3 - 9% (29), Category 4 - 14% (46)¹⁶. 77% of the subjects were in category 1 or 2.

Lung-RADS Categories in our study: Category 1 - 84.9% (1273 subjects), Category 2 - 8.7% (131 subjects), Category 3 - 3.9% (58 subjects), Category 4 - 2.5% (38 subjects). Lung nodules / mass found in 22.3% (335 subjects among 1500; included calcified and <6mm nodules other than screen positive nodules). Majority (84.9%) were in category 1.

Screen positivity rate in our Indian study is 6.4% (mass lesion /at least one non-calcified nodule of 6 mm or more). Even though, the screen positivity rate in our study is reasonable but, still, it is low compared to other studies across the world. Screen positivity rate of various studies across different countries are as follows:

USA - The National Lung Screening Study (NLST) 27% (non-calcified nodule of at least 4 mm in diameter)³,

Canada - LDCT screening demonstration project by British Columbia Cancer agency 46% (at least one non-calcified nodule)⁵,

Brazil - Brazilian Lung Cancer Screening Trial (BRELT1) 39.5% (nodules >4 mm) and 18.4% (nodules 6 mm or larger)⁶,

Italy - MILD project 15.3% and 13.7% in annual & biennial LDCT groups (nodule \geq 4.8mm)⁸,

France - 45.2% (at least one non-calcified nodule)²,

Korea - 35% (at least one non-calcified nodule)¹³,

Taiwan - 38.3% (any non-calcified nodule \geq 4 mm)¹⁴.

Lung cancer detection rate in our Indian study is 0.13% (2/1500), low when comparing with the rates of studies across different countries:

USA - The National Lung Screening Study (NLST) 2.4% (649/26722)³,

Canada - LDCT screening demonstration project by British Columbia Cancer agency 3.7% (21/561)⁵, Brazil - Brazilian Lung Cancer Screening Trial (BRELT1) 1.2% (10/790)⁶,

Italy - MILD Project 2.5% (29/1152) and 1.7% (20/1149) in annual and biennial LDCT groups⁸,

France - 2.4% (8/336)²,

Korea - 0.36% (24/6406)¹³,

Taiwan - 1% (34/3339)¹⁴.

Even though, the total screen positivity of our study was 6.4%; total lung cancer cases detected on follow-up is only 2 among the 1500 subjects screened. There is high chance for false positive results during LDCT scans for lung nodules in countries like India, where tuberculosis has been endemic. Many of the nodules detected might have been tuberculomas / granulomas. This was also stated in the results of Korean Lung Cancer Screening (K-LUCAS) Project. As per K-LUCAS Project, LDCT screening in an at risk population for lung cancer in a tuberculosis endemic country may be less effective due to false positive results from

tuberculosis sequelae and reduced specificity of LDCT screening for lung cancer. Among 11394 at risk subjects evaluated in K-LUCAS Project, even though positive results were found in 1868 subjects (16%), lung cancer was seen only in 65 (0.6%). No association found between tuberculosis sequelae and lung cancer. Specificity of Lung-RADS was higher for those without tuberculosis sequelae than those with tuberculosis sequelae¹⁷.

There were many limitations for our study. Specific inclusion criteria was not there for the study. Study was done among those who opted for LDCT as screening method for detection of lung cancer as part of wellness general health check-up. High risk subjects were not specifically selected for the study. Study used retrospective data of the LDCT screening scans reported by various practicing radiologists; hence, variability in reporting might be there. Also, majority of subjects were lost for follow-up. Hence, study results may not be accurate for the population.

CONCLUSION

LDCT screening has been highly sensitive in the detection of the lung nodules, in consistent with the studies done worldwide. However, the number of lung cancer cases identified among total subjects was very low. Even though, the study is limited by various factors, it still gives a cue that LDCT screening for lung nodules may result in high false positive results in countries like India where tuberculosis has been endemic. Hence, further detailed studies must be carried out among high risk subjects with proper follow-up before introducing/ incorporating LDCT into screening policies in developing countries like India.

Declaration by Authors

Ethical Approval: Approved

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