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ROLE OF LOW-DOSE COMPUTED TOMOGRAPHY IN THE EVALUATION OF PULMONARY NODULES AND ITS CORRELATION WITH STANDARD-DOSE COMPUTED TOMOGRAPHY AND COMPUTED TOMOGRAPHY GUIDED FINE NEEDLE ASPIRATION CYTOLOGY

Radiodiagnosis

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ABSTRACT

Background: The necessity for early detection of pulmonary nodules to reduce the lung cancer burden needs a modality using the principle "as low a radiation dose as can reasonably be achieved" (ALARA) at the same time with acceptable image quality. Low-dose computed tomography (LDCT) with radiation dose equivalent to chest X-ray is an excellent tool in the early diagnosis as well as follow-up of pulmonary nodules.

Objective: To determine the sensitivity of the low-dose helical multidetector computed tomography (MDCT) in the detection and evaluation of pulmonary nodules in comparison with standard-dose helical MDCT and to correlate the imaging findings of the pulmonary nodules assessed by the low-dose helical MDCT with helical MDCT guided fine needle aspiration cytology.

Materials and Methods: This is a single-center cross-sectional analytical study, conducted over a period of two years on 53 adult patients, at Department of Radiodiagnosis in collaboration with Department of Respiratory Medicine and Department of Pathology in a medical institute at Imphal. All patients were subjected to both standard-dose and low-dose helical MDCT with the same CT machine and images were compared in terms of number of nodules, nodule size, and density. Final diagnosis was done by cytological examination by helical MDCT guided FNAC of the pulmonary nodules wherever possible. Radiation issues in terms of dose-length product and effective radiation dose were also compared between low-dose and standard-dose CT.

Results: Sensitivity of the low-dose helical MDCT against standard-dose helical MDCT in detecting < 5 mm sized nodules was 86.67% and 100% for ≥ 5 mm sized nodules. Overall sensitivity of low-dose helical MDCT in detecting pulmonary nodules was 99.44% as against standard-dose helical MDCT with coefficient of determination (R^2) for number of nodules detected per patient measuring 99.7%. Sensitivity of low-dose CT as against standard-dose CT in detecting both benign and indeterminate calcified nodules was 100% and for non-calcified, solid and sub-solid nodules were 98.26% and 100% respectively. Mean effective radiation dose was significantly lower in low-dose helical MDCT in comparison to standard-dose helical MDCT (p value = 0.000) in both male and female patients and total study population with 75.33% reduction in the effective radiation dose.

Conclusion: Low-dose helical MDCT can reliably be used in the evaluation as well as follow-up of pulmonary nodules with reduced radiation dose.

KEYWORDS

Low-dose Helical MDCT, Standard-dose Helical MDCT, Dose-length Product, Effective Radiation Dose.

1. Introduction

Lung cancer is one of the major and ideal health problems for screening because of adequate understanding of the natural history of the disease, presence of high risk population, relatively asymptomatic nature of the disease in the early stage and availability of the better curative options and better prognosis when diagnosed in the early stage.[1] The high inherent tissue contrast and relatively low radiation absorption of the lungs allow for substantial radiation dose reduction in computed tomography (CT) with acceptable image quality due to the recent advances in CT.[2,3,4]

Advances in surgical, radiotherapeutic, and chemotherapeutic approaches have been made for the lung cancer but the long-term survival rate remains low.[5]The most effective treatment for lung cancer is surgical resection. However, since early curable lung cancers usually produce no symptoms and are often missed at chest radiography, many tumors are not resectable at the time of diagnosis. Thus, the prognosis is poor. However, because the cure rate for non–small cell lung cancers smaller than 20 mm in diameter has been reported to be greater than 80%, earlier and more certain detection with more effective screening methods can be expected to improve the cure rate.[6]

Findings from comparative studies of chest radiography and computed tomography (CT) have shown CT to be the best imaging modality for the detection of pulmonary nodules in vivo. Its role has continuously expanded, particularly since the introduction of spiral technology.[2]

Although effective mass screening of high-risk groups could potentially be of benefit, randomized trials of screening with the use of chest radiography with or without cytologic analysis of sputum specimens have shown no reduction in lung-cancer mortality. Molecular markers in blood, sputum, and bronchial brushings have been studied but are currently unsuitable for clinical application. Computed tomography (CT) is generally accepted as the most accurate imaging technique for the detection of pulmonary nodules. Furthermore, helical CT allows scanning of the entire lung during a single breath hold. Thus, attempts have recently been made to apply helical CT as a primary screening method for lung cancer.[5]

The potential of "Low dose CT" of the lungs was first critically evaluated by Naidich DP et al[7] in 1990. Study conducted in two patients with normal-appearing lungs and 10 patients with a wide diversity of underlying parenchymal abnormalities. Standard-dose CT taken with 120 kVp, 140 mA, 2-second scan time, 10 mm thick sections and low-dose CT taken with 10 mA with all other parameters held constant. Study depicted that at all levels of the thorax, visualization of parenchymal structures was not affected by decreasing the milliamperage.[7]This is one of the milestones in the CT scan history, which provided an alternative tool for screening lung cancer at high-risk population and threw light in reducing the risk of radiation particularly in the paediatric population.

Therefore this study was undertaken to determine the sensitivity of the low-dose helical multidetector computed tomography with appropriate scan parameters achievable with our CT machine in the detection and assessment of the pulmonary nodules and its comparison and correlation with standard-dose helical multidetector computed tomography so that low-dose helical multidetector computed tomography can be used as a screening tool in the early detection of lung cancer thus will reduce the mortality of the same. The cytological reports were considered as reference standard wherever possible. This study provides evidence that low-dose helical MDCT scan can detect

early stage lung cancers in a population at varied lung cancer risk including people less than 50 years old.

2. Materials and Methods

2.1 Study design

This was a cross-sectional analytical study, which was carried over a period of two years from September 2015 to August 2017 on 53 adult patients (39 male and 14 female patients), in a medical institute at Department of Radiodiagnosis in collaboration with Department of Respiratory Medicine and Department of Pathology. The study was commenced only after the approval from the Research Ethics Board of this institute. Informed consents were obtained from all the patients before the study.

Clinical history of each case including age, sex, marital status, occupation, religion, address, chief complaints with duration, personal history, past history and the details of the general and systemic examinations of the patients were collected from the Department of Respiratory Medicine. Routine laboratory tests were done in all patients and they were subjected to low-dose helical MDCT scanning immediately followed by standard-dose helical MDCT scanning of chest.

2.2. Image acquisition and parameters

All the chest examinations were performed with the same Philips Brilliance 64-slice CT Machine, manufactured in Netherlands on 9/2007 with model serial number 10311 on suspended full inspiration in a medical institute at Department of Radiodiagnosis.

The patients underwent low-dose helical MDCT of the chest (50 mA, 120 kV, collimation 64x0.625, pitch 0.80, rotation time 0.5 s/rotation, and acquisition slice thickness of 2 mm) followed by a standard-dose helical MDCT with a tube current of 200 mA. The remaining parameters were kept constant as in low-dose helical MDCT. All the images obtained with both low dose and standard dose helical MDCT were stored separately. Helical MDCT guided fine needle aspiration cytology (FNAC) of the pulmonary nodules was taken from the patients wherever possible. The computed tomography dose index (CTDI) of the scanner per 100 mAs was 9.5 mGy at periphery and 3.6 mGy center of a 32 cm body phantom for a collimation of 5 mm at 120 kV.

2.3. Dose estimates

The radiation dose info chart available at the end of scanning was analysed and data on Dose Length Product (DLP) in mGy.cm were recorded separately for low-dose helical MDCT and standard-dose helical MDCT. The effective dose for every scan due to the low-dose and the standard-dose helical MDCT scans was calculated using one practical formula: Effective dose (in mSv) = DLP x conversion factor [where conversion factor is 0.014 for helical multidetector computed tomography of chest][8]. The mean effective dose from low-dose helical MDCT and standard-dose helical MDCT were compared at the end.

2.4. Image analysis

Initially the sets of images obtained at low-dose helical MDCT scans from all the patients were assessed for any rounded or ovoid lesion within the lung parenchyma suggestive of pulmonary nodule. The observer was blinded about the images obtained at standard-dose helical multidetector computed tomography scan from the patients at this point of time in order to avoid the bias.

A number was given to each nodule from top to bottom for each lung. Any artefacts degrading the image and obscuring pulmonary nodules was also assessed. The nodule size was measured electronically on the monitor. Particular attention was paid to the assignment of nodules into two size categories as < 5 mm and ≥ 5 mm with respect to the risk of malignancy. With respect to the density, pulmonary nodules were broadly classified into calcified and non-calcified nodules. Calcified nodules were divided into nodules with benign calcification pattern such as central, diffuse, laminated and popcorn and nodules with indeterminate calcification. Non-calcified nodules were divided into a) Solid b) Pure ground-glass and c) Part-solid ground-glass. Solid nodules were defined as nodule densities completely equal or higher than pulmonary vessel. Pure ground-glass opacity nodules were the nodules with preservation of the pulmonary vascular and bronchial markings without complete obscuration of parenchyma. Part-solid ground-glass opacity nodules were nodules that have both ground-glass and solid components.

In the second step, after assessing all the images obtained at low-dose helical MDCT scan from the patients, the images obtained at standard-dose helical MDCT scan from the patients were assessed. Then in the third step, for each patient images obtained both at low and standard-dose helical multidetector computed tomography were compared for the number, size, and density of the nodules. For those seen at both helical MDCT parameters, attention was paid for any discrepancy in size.

Finally the imaging findings detected by low-dose and standard-dose helical MDCT were compared with cytological findings wherever possible and data were used for determining cancer detection rate of low-dose as well as the standard-dose helical MDCT.

2.5. Data management and statistical analysis

Outcome variable in this study is the sensitivity of the low-dose helical MDCT in the detection and evaluation of pulmonary nodules. Specificity, positive and negative predictive values could not be calculated for individual nodules in lungs with multiple lesions since true-negative and false-positive values could not be recorded. Collected data were checked for consistency and completeness. Summarization and analysis was carried out using descriptive statistics like percentages, means and standard deviation, independent samples T test, and coefficient of determination were used to calculate the statistical significance between the variables.

3. Results

Images obtained from low-dose CT (LDCT) and standard-dose CT (SDCT) were compared to determine the sensitivity of the low-dose CT against standard-dose CT in terms of size, number and density of the nodules and results were drawn. Radiation issues in terms of dose-length product and effective radiation dose were also compared between low-dose and standard-dose CT and conclusions were drawn. Final diagnosis was done by cytological examination by helical MDCT guided FNAC of the pulmonary nodules wherever possible and benign and malignant pathologies were described in terms of size and demographic data such as age, sex and etiological distribution. Cancer detection rate from the study population was also obtained.

No statistically significant difference noted in the mean size of pulmonary nodules measured with low-dose CT in comparison with standard-dose CT (p value = 1.00). Mean size of the malignant nodules (25.77 ± 2.862 mm) was significantly higher than mean size of the benign nodules (21.85 ± 6.323 mm) with p value of 0.004.

The number of nodules detected by both low-dose and standard-dose CT was same in nodules measuring ≥ 5 mm in size (n=162) with 100% sensitivity. Nevertheless, sensitivity of low-dose CT in detecting nodules < 5 mm in size was 86.67%. Overall sensitivity of LDCT in detecting pulmonary nodules was 99.44% as against SDCT with coefficient of determination (R^2) for number of nodules detected per patient measuring 99.7% (Table 1 and Fig. 1).

Sensitivity of low-dose CT as against standard-dose CT in detecting both benign and indeterminate calcified nodules was 100% and for solid and sub-solid (pure ground-glass and part-solid ground-glass) nodules were 98.26% and 100% respectively (Table 2, Fig. 2, 3 and 4).

Benign pulmonary nodules (n=40) were more commonly encountered than malignant nodules (n=13) in the study population accounting for 75.47% of the study population. Of the malignant nodules, adenocarcinoma was the most common malignant neoplastic pathology accounting for 13.20% of the patients (Table 3).

Of the 53 patients who underwent low-dose and standard-dose CT, 13 patients were diagnosed with malignant pulmonary nodules accounting for the cancer detection rate of 24.52% in both low-dose and standard-dose CT.

The mean BMI of the study population was 23.55 ± 2.77. Only 2 patients were underweight (< 18.5) constituting 3.77% of the study population. Most of the study population had fallen under normal (18.5 – 22.9) weight category constituting 35.85% of the study population followed by overweight (23.0 – 24.9) and obese (≥ 25.0) patients accounting for 32.08% and 28.30% of the study population (Fig. 5). The tube current was not increased to any patient since the maximum BMI of the study population was 30.91 only and the satisfactory image quality was obtained with 50 mA in the entire weight category group.

The mean Dose Length Product (DLP) for the chest produced by our CT machine with low-dose CT and standard-dose CT protocols were 120.21 mGy.cm ± 11.45 and 486.45 mGy.cm ± 71.18 respectively. Mean Dose-Length Product was significantly lower than in low-dose helical MDCT in comparison to standard-dose MDCT with *p* value of 0.000 (Table 4). Mean effective radiation dose was significantly lower in low-dose helical MDCT in comparison to standard-dose helical MDCT (*p* value = 0.000) in both male and female patients and total study population with 75.33% reduction in the effective radiation dose (Table 5).

Few incidental findings were also noted in the study population on both LDCT and SDCT (Table 6). Most frequently encountered incidental findings were in the respiratory system (75.47% of patients, n=40) followed by cardiovascular (71.70% of patients, n=38) (Fig. 6), hepatobiliary (37.74% of patients, n=20), genitourinary (26.42% of the patients, n=14) and endocrine (18.87% of patients, n=10). Most commonly reported incidental finding was aortic calcification accounting for 67.92% of the patients (n=36).

4. Discussion

Ability to detect and categorize the pulmonary nodules is affected by the nodule size, nodule density and image acquisition parameters. No statistically significant difference noted in the mean size of the pulmonary nodules measured with low-dose CT in comparison with standard-dose CT (*p* value 1.000). This is in concordance with the study by Ono K et al[10] who showed 100% concordance rate between low-dose and standard-dose CT in nodule size measurement.

The number of nodules detected by both low-dose and standard-dose CT was same in nodules measuring ≥ 5 mm in size (n=162) with 100% sensitivity. Nevertheless, sensitivity of low-dose CT in detecting nodules < 5 mm in size was 86.67%. Overall sensitivity of LDCT in detecting pulmonary nodules was 99.44% as against SDCT with coefficient of determination (R^2) for number of nodules detected per patient measuring 99.7%. This is in agreement with the study by Karabulut N et al[3] who showed 88% sensitivity in detecting nodules measuring < 5 mm and 97% for nodules measuring > 5 mm and with the study by Gartenschlager M et al[11] and Vardhanabhuti V et al.[12] Higher sensitivity of low-dose CT in detecting number of nodules may be due to the thinner collimation (64 x 0.625 mm) and lower pitch value (0.8) used in our CT machine.

Sensitivity of low-dose CT in detecting both benign and indeterminate calcified nodules was 100% over standard-dose CT. Of 9 nodules with indeterminate calcification, 5 nodules diagnosed as benign and rest 4 nodules were malignant. Sensitivity of low-dose CT in detecting solid and sub-solid (pure ground-glass and part-solid ground-glass) nodules were 98.26% and 100% respectively. These results are in concordance with the study by Ono K et al[10] and Vardhanabhuti V et al[12].

Overall cancer detection rate was 24.52% with adenocarcinoma was the most common malignant neoplastic pathology in our study. These results are in agreement with the study by Ono K et al[10], Chen CY et al[18] and Mohan A et al[19] with relatively higher cancer detection rate achieved in our study probably due to the small sample size.

No evidence of artefacts degrading the image quality that would compromise the nodule detection noted in any case with low-dose CT. This is in agreement with the study by Karabulut N et al.[3]

The diagnostic acceptability for nodule detection was not reduced even in the patient with maximum BMI (30.91) and the tube current was not increased to any patient and satisfactory image quality was obtained with 50 mA in all the weight category groups. This is in agreement with the study by Manowitz A et al[8] who achieved satisfactory image quality for patients even with the BMI value of 30-34.9 with 40 mA. But further reduction from 50 mA was not used in our study since Diederich S et al[2] reported reduced sensitivity for detecting nodules measuring ≤ 5 mm for tube current settings < 50 mA.

Our study showed that LDCT can also detect other pulmonary and extrapulmonary incidental findings of variable clinical importance since some of them may pave the way for further investigations and management of the same. Previously reported prevalences of incidental findings were 8% in the Van de Wiel JC et al[13] screening trial and 19% in Kucharczyk et al[14] screening trial. In our study, most frequently encountered incidental findings were in the respiratory system (75.47% of patients, n=40) followed by cardiovascular (71.70% of patients, n=38), hepatobiliary (37.74% of patients, n=20), genitourinary (26.42% of the patients, n=14) and endocrine (18.87% of patients, n=10). Most commonly reported incidental finding was aortic calcification accounting for 67.92% of the patients (n=36). These results are in agreement with the recent study by Morgan L et al[15] who reported incidental findings in respiratory system in 69.6% of the patients followed by cardiovascular system (67.5% of patients).

The main concern for the screening of lung cancer with CT is the radiation-induced carcinogenesis. Previously it was thought that risk of radiation induced malignancy diminished with increasing age of exposure, because children have greater number of dividing cells, thus they are more radiosensitive and also because of longer life expectancy thus more years to develop cancer. Now it is realized that, radiation risks determined by radiation-induced premalignant cells (initiation processes) for younger individuals whereas for elderly individuals by promotion of preexisting premalignant cells. Radiation-related excess relative risk (ERR) for cancer induction decreases with increasing age at exposure only until exposure ages of 30-40 years according to the analyses of Japanese atomic bomb survivors. Initiation processes are the predominant factor for radiation-related breast cancers whereas promotion of preexisting premalignant cells may dominate for radiation-related lung cancer. Therefore, with age at all exposures, radiation-induced breast cancer risks decreases with age whereas this is not the case with radiation-induced lung cancer risks. The excess lifetime risks of lung cancer may peak at around age 50 years, the most likely age for individuals to undergo CT screening.[16]

In our study, mean Dose-Length Product (DLP) was significantly lower in low-dose helical MDCT (120.21 ± 11.45) in comparison to standard-dose MDCT (486.45 ± 71.18) with *p* value of 0.000. The mean effective radiation dose for male and female patients were 1.686 ± 0.172 mSv and 1.674 ± 0.126 mSv respectively in low-dose CT and for standard-dose CT, 6.788 ± 1.126 mSv and 6.871 ± 0.512 mSv respectively. Mean effective radiation dose (ERD) for the total study population was 1.683 ± 0.160 mSv in low-dose CT as against 6.810 ± 0.997 mSv in standard-dose CT. Hence, mean effective radiation dose was significantly lower in low-dose helical MDCT in comparison to standard-dose helical MDCT (p value = 0.000) in both male and female patients and total study population. Hence, there was 75.33% reduction in the effective radiation achieved with low-dose CT using the tube current of 50 mA. This is in concordance with the study by Larke FJ et al[17] who achieved the mean effective radiation dose of 2 mSv with low-dose CT.[17]

Major limitation of this study is the short study period compared with NLST (National Lung Screening Trail) and other ongoing European randomized lung cancer screening trial and thus the overall cancer detection rate must be underestimated. Second major limitation is the majority of the nodules detected in this study are relatively large nodules with solid and calcified components. And finally, not all patients with positive baseline CT findings or CT guided fine needle aspiration cytology findings received regular follow-up to detect the interval growth of the nodules due to the short duration of the study period.

Conclusion

Low-dose helical MDCT can reliably be used in the evaluation of pulmonary nodules with respect to number, size, and density of the nodules with no significant degradation of the image quality at the same time with almost 75% reduction in the effective radiation dose to the patient in comparison to the standard-dose helical MDCT. Thus, it can be used in patients with high risk of lung cancer as a screening tool for the early detection of suspicious nodules hence cure rate of the lung cancer can be increased with early surgical resection. In addition detection of few other pulmonary and extra-pulmonary findings with low-dose CT may pave the way for early further investigations and management of the same.

Conflicts of interest: Nil.

Table 1 Number of Nodules

Size	Number of nodules			Sensitivity of LDCT
	Both by LDCT and SDCT	Only by LDCT	Only by SDCT	
< 5 mm (n=15)	**13**	**0**	**2**	**86.67%**
≥ 5 mm (n=162)	**162**	**0**	**0**	**100%**
TOTAL (n=177)	**175**	**0**	**2**	**99.44%**

Table 2 Nodule density

Nodule density	By both LDCT and SDCT	Only by LDCT	Only by SDCT	Sensitivity of LDCT
Calcified (n=53)	**53**	**0**	**0**	**100%**
Benign pattern	44	0	0	100%
Indeterminate	9	0	0	100%
(i) Benign	5	0	0	100%
(ii) Malignant	4	0	0	100%
Non-calcified (n=124)	**122**	**0**	**2**	**98.39%**
Solid (n=115)	113	0	2	98.26%
Sub-solid (n=9)	9	0	0	100%
(i) Pure GGO*	2	0	0	100%
(ii)Part-solid GGO*	7	0	0	100%

GGO* Ground-Glass Opacity

Table 3 Etiological distribution

Pathologies	Frequency (n)	Percentage (%)
Number of Patients Diagnosed with Malignant Nodules	**13**	**24.52**
Adenocarcinoma	7	13.20
Small cell carcinoma	3	5.66
Squamous cell carcinoma	3	5.66
Number of Patients Diagnosed with Benign Nodules	**40**	**75.47**

Table 4 Dose Length Product (DLP)

Modality	N	Minimum	Maximum	Mean	Standard Deviation	p value
DLP (LDCT)	53	103	143	120.21	11.45	0.000
DLP (SDCT)	53	243	675	486.45	71.18	

Table 5 Effective Radiation dose (ERD)

Gender	ERD	LDCT	SDCT
Female	Mean	1.674	6.871
	N	14	14
	Std. Deviation	0.126	0.512
	p value	0.000	
Male	Mean	1.686	6.788
	N	39	39
	Std. Deviation	0.172	1.126
	p value	0.000	
Total	Mean	1.682	6.810
	N	53	53
	Std. Deviation	0.160	0.997
	p value	0.000	

Table 6 Incidental findings noted on LDCT

System involved	Frequency (n)	Percentage (%)
Respiratory System	**40**	**75.47**
Emphysema	26	49.06
Bronchiectasis	6	11.32
Atelectasis	10	18.87
Pleural effusion	10	18.87
Mediastinal adenopathy	20	37.74
Pulmonary arterial hypertension	4	7.55
Cardiovascular	**38**	**71.70**
Coronary arterial calcification	20	37.74
Aortic calcification	36	67.92
Genitourinary	**14**	**26.42**
Renal calculi	12	22.64
Renal cysts	6	11.32
Endocrine	**10**	**18.87**
Thyroid nodules	10	18.87
Hepatobiliary	**20**	**37.74**
Hepatic cysts	8	15.09
Hepatic calcification	4	7.55
Gallstones	12	22.64

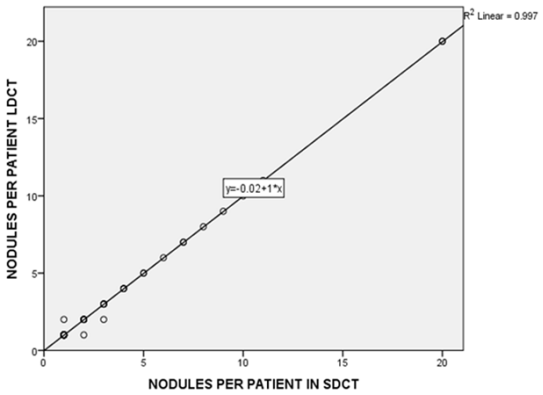


Figure 1: Correlation between number of pulmonary nodules detected by SDCT and LDCT. Scatter plot showing the relationship between the number of pulmonary nodules detected with standard-dose CT and low-dose CT. The solid line represents the complete agreement between the two modalities with coefficient of determination (R2) measuring 99.7%.

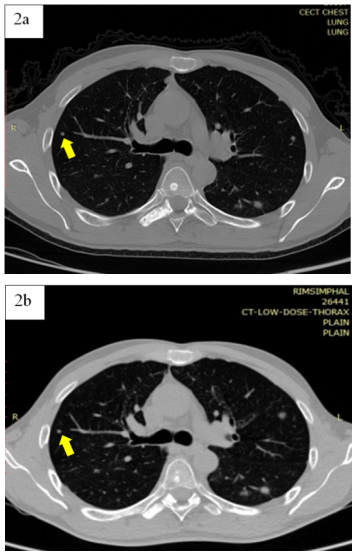


Figure 2: Example of a 3 mm sized solid nodule (arrows) involving the right upper lobe, which is conspicuous on both standard-dose (2a) as well as low-dose (2b) axial non-contrast chest CT images, despite the small size and vicinity to the vessel.

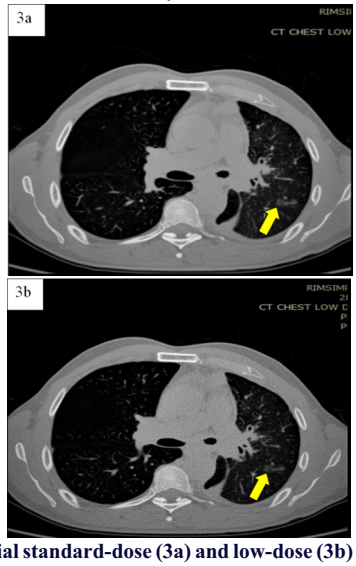


Figure 3: Axial standard-dose (3a) and low-dose (3b) non-contrast chest CT images taken from a 45-year-old male patient, show left upper lobe pure ground-glass nodule (arrows) with vascular structures inside the nodules, conspicuous on both the images. Final diagnosis was small cell carcinoma of the lung.

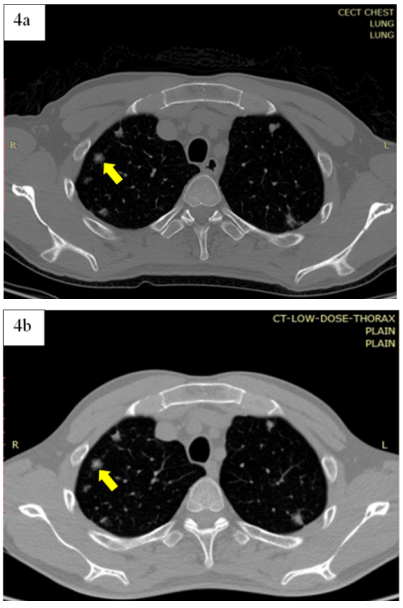


Figure 4: Example of a part-solid nodule (arrows) involving the right upper lobe, which is visualized clearly in both standard-dose (4a) as well as low-dose (4b) axial non-contrast chest CT images. Final diagnosis was adenocarcinoma of the lung.

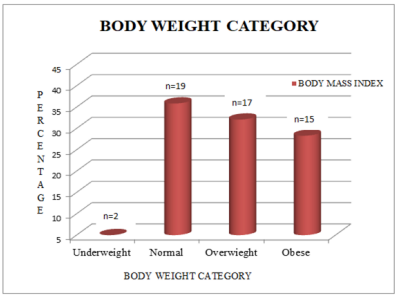


Figure 5: Bar diagram shows the Body Weight Category of the study population

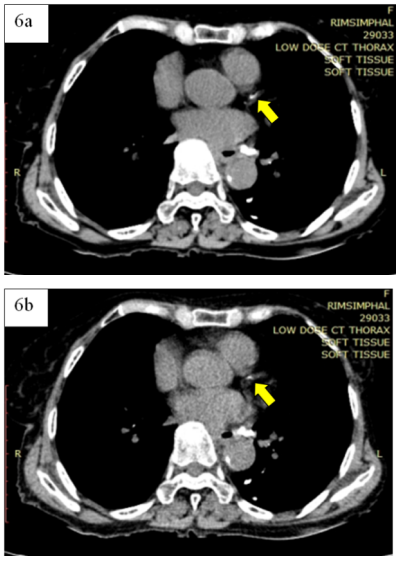


Figure 6: Wall calcification involving the left anterior descending artery (arrows) which is conspicuous on both standard-dose (6a) as well as low-dose (6b) axial non-contrast chest CT images in an 80-year-old female patient in our study as an incidental finding.

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