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ORIGINAL ARTICLE

Incidental Pulmonary Nodules Are Common on CT Coronary Angiogram and Have a Significant Cost Impact

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Background Computed tomography (CT) coronary angiogram (CTCA) is commonly used for diagnostic evaluation of low-moderate risk patients due to its excellent performance and cost-effectiveness. However, previous cost analyses have not factored in the burden of management of pulmonary nodules, which are a common occurrence. We sought to describe the frequency and characteristics of lung nodules on CTCA in an Australian tertiary hospital, and to assess cost impacts.

Methods Consecutive CTCAs performed in the calendar year 2012 were retrospectively identified from the imaging department database. Subjects were excluded if they were under the age of 35, had known malignancy or findings identified prior to CTCA. Patients were stratified on smoking history and nodule size.

Results Of the 2479 CTCAs included, full-field imaging revealed nodules in 358 patients (13.9%). The nodules were generally small (73% <6 mm), multiple (63%) and in the lower lobe (83.4%). There was no significant difference when stratified for smoking, with 60% of nodules detected in never-smokers. A minimum of 445 subsequent scans was required for nodule surveillance, resulting in an additional overall cost of $63.62 per CTCA. Limited-Field-of-View (L-FOV) would have identified only 22 nodules, with a cost of $6.14 for every CTCA performed, a cost saving of $57 per patient.

Conclusions Indeterminate pulmonary nodules are a common incidental finding on CTCA and prevalence appears to be independent of smoking status. There is a consequent significant cost burden that has not previously been recognised. Use of L-FOV reduces the number of nodules identified, with a significant cost benefit, but this has to be balanced against the ethical and medico-legal issues inherent in not reconstructing the irradiated lung.

Keywords Computed tomography coronary angiography • Solitary pulmonary nodules • Multiple pulmonary nodules • Cost analysis

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Introduction

Incidental pulmonary findings are well described following imaging of the thorax for various indications including CT coronary angiograms (CTCAs). CTCAs are increasingly used for the investigation of low-moderate risk patients suspected of having coronary artery disease with a four-fold increase in studies performed from 2011 to 2015 [1,2]. There is a substantial literature supporting the use of CTCA as a rule-out test due to its excellent diagnostic performance and cost-effectiveness [3–5]. However, studies suggesting CTCA may be a cost-effective screening strategy for the investigation of troponin negative patients with chest pain have not included downstream cost implications of extra-cardiac findings [6].

Incidental pulmonary nodules are the commonest extra-cardiac finding on CTCA ranging from 8 to 18%. The incidence of malignancy in such nodules is very low, and lesions are most frequently asymptomatic and clinically irrelevant [7]. While the 2005 Guidelines published by the Fleischner Society have been a standard for many years, the group has now published updated guidance with substantial new data on which to base the recommendations [8,9]. These new guidelines will have the effect of reducing the total number of surveillance scans as compared to those from 2005, but even adherence to these guidelines may result in significant health care costs, thus impacting cost-effectiveness estimates for CTCA.

While scans acquire skin-to-skin data, some authors have suggested that reconstructing images to only include a Limited-Field-of-View (L-FOV) lung parenchyma within 1 cm of the heart, not only improves spatial resolution of the coronary arteries, but will also reduce the detection of incidental lung nodules [10]. This approach carries with it a number of medico-ethical as well as legal issues that have been previously debated [11–14].

We sought to determine the prevalence of pulmonary nodules in patients undergoing CTCA in an Australian tertiary care hospital, to characterise the population effected, and to determine the cost burden resulting from these incidental findings. In addition, we have evaluated the economic impact of routine use of L-FOV rather than Full-FOV.

Methods

Study Setting

This cohort comprised consecutive CTCAs performed in the calendar year 2012 at a tertiary care referral hospital in Melbourne, Australia. The scans were retrospectively identified from the imaging department database by manual review of reports. Subjects were excluded if they were under the age of 35, had no data recorded from the examination, or had known malignancy or other pulmonary findings identified prior to CTCA. The study was approved by the local Human Research Ethics Committee.

Data Collection

Demographic data on patients were obtained from clinical records. Patients were stratified according to smoking history into two groups: ever-smokers including current smokers, ex-smoker (quit less than 12 months ago), ex-smoker (quit more than 12 months ago); and never smoker. Nodule characteristics including size, spiculation and location were collected as reported. Analysis was performed on a per patient basis. Differences between groups was assessed with Fisher's exact test using GraphPad Prism version 7.00 for Mac OSX, (GraphPad Software, La Jolla California USA, www.graphpad.com).

Performance of CTCA

Computed tomography coronary angiography was performed using the Toshiba Aquilion 320 slice CT (Toshiba Medical Systems Corp. Japan). Acquisitions were then co-reported with a radiologist assessing lung parenchyma and non-cardiac findings with a cardiologist and radiologist co-reporting cardiac findings. Unsuspected pulmonary findings were communicated back to the referring doctor for assessment and management as indicated.

Field-of-View

A full FOV is obtainable from every CT scan which includes skin-to-skin data in the area imaged [15]. Previous analyses have shown approximately 70% of the lung parenchyma is imaged although this can vary depending on patient anatomical factors [11,16], excluding lung apices and, variably, lung bases. At the discretion of the radiology provider, a small (Limited) FOV—approximately 25 cm—can be cropped around the heart (Figure 1). This does not alter the radiation exposure of the examination.

Economic Analysis

Cost estimates were derived from the Medicare Benefits Schedule as of 2016 [17] without consideration of out of pocket fees and are presented in Table 1. An estimation of the required amount of physician clinic reviews can be obtained using CT scans as a surrogate for physician review with a CT chest with contrast assumed to be ordered at baseline to accurately define the entire lung parenchyma and mediastinum, with subsequent scans being without contrast.

The number of subsequent scans was based on published Fleischner Society guidelines that stratify according to nodule size and risk factors to recommend the frequency and number of CT chest imaging repeats—this is outlined in Table 2. No account is made for the interval development of new nodules on serial CT scans (which occurs in 20% of scans) [18].

Due to the diverse possible investigational pathways for nodules >8 mm, we have standardised the follow-up to three additional scans only. Positron emission tomography (PET), bronchoscopy, percutaneous biopsy and surgical resection, as well as the disutility associated with the finding of pulmonary nodules, are not amenable to reliable estimation, and

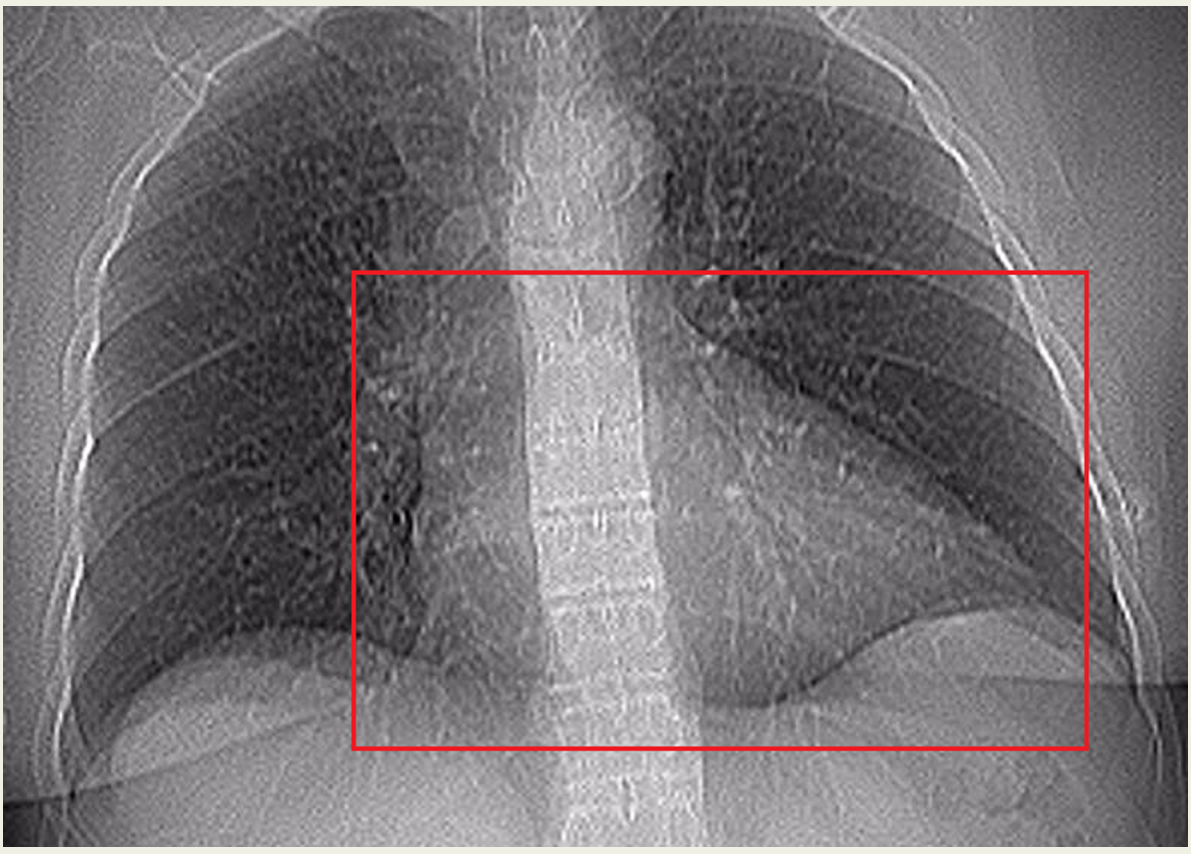

Figure 1 CT scout with Full FOV and approximating Limited FOV (red square).

Table 1 Costs included in economic analysis; Medicare Benefits Schedule Online 2016.

Procedure	Item	85% Medicare rebate
CT Coronary arteries	57360	$620.50
CT Chest with contrast	56307	$340
CT Chest without contrast	56301	$250.75
Physician Review (Initial)	110	$128.30
Physician Review (Repeat)	116	$64.20

Abbreviation: CT = computed tomography.

have not been considered in this analysis. Respiratory function testing may be performed in clinical assessment of such patients but has not been included in the economic modelling.

Results

For the calendar year 2012, 2539 CTCAs were performed for the investigation of suspected coronary artery disease, with 2479 meeting inclusion and no exclusion criteria. The cohort showed a slight male predominance (51.5%) with a median age of 59 (IQR 51–68). 345 (13.9%) subjects had nodules identified at the time of CT scanning on full-field imaging. Of those with nodules, 129 were found to

Table 2 Additional scans required including initial formal CT chest and surveillance according to Fleischner Society recommendations.

Nodule size	Low Risk Patient	Low Risk Patient With High Risk Nodule	High Risk Patient
<6 mm	0	0	2
6–8 mm	2	3	3
>8 mm	3	3	3

Abbreviation: CT = computed tomography.

Table 3 Patient demographics of total cohort and those included in the analysis.

	Total	Nodule	No Nodule
Total scans	2539	388 (15.3%)	2479 (84.7%)
Scans for eligible patients*	2479	345 (13.9%)	2134 (86.1%)
Age – Median (IQR)	59 (51–68)	61 (54–69)	59 (51–67)
Smoking (ever smokers)	990 (39.9%)	141 (40.9%)	849 (39.8%)
Male	1277 (51.5%)	175 (50.7%)	1102 (51.6%)

*Patients excluded if age <35 years, had known malignancy or previously identified pulmonary pathology, or for whom no data was recorded from the scan.

have a single nodule, with the remaining 216 (63%) having multiple nodules. Patient demographics are presented in Table 3. Importantly, more than half the scans were performed on never-smokers, and even assuming fulfilment of smoking criteria (> 30 pack years and quit <15 years) only 20% would have been eligible for lung cancer screening as per the National Lung Screening Trial (NLST) criteria [19].

Nodules were generally small (73% <6 mm; 10.4% >8 mm) and there was a predominance of lower lobe nodules (83.4%). Of the whole cohort, the prevalence of upper lobe nodules did not differ between ever-smokers and never-smokers (2.9% vs 1.9%; p = 0.10). The prevalence of nodules did not differ significantly between ever-smokers and never-smokers (14.2% vs. 13.7%; p = 0.72), nor between males and females (13.7% vs. 14.14%; p = 0.77).

Recommendations formulated as part of the Fleischner criteria (Table 1) propose that, for each nodule found on CTCA, one or two extra CT scans are required to establish a pulmonary nodule's stability. In the presence of multiple nodules surveillance (and costs) are determined by the largest nodule. Based on these considerations we calculated that, in our cohort of 2479 patients, a minimum of 445 additional scans were indicated following the initial finding of a pulmonary nodule. The total cost was calculated at $157,726.10. This equates to an extra $63.62 for every CTCA or $457.18 for every scan with a nodule identified (Table 4).

Limited-Field-of-View

Reducing the extent of parenchyma examined to a limited FOV would have identified 22 of the 345 scans with nodules identified (6.4%) that is 0.9% of the original 2479 cohort. The reduced number of identified nodules resulted in a reduction in the number of additional scans required to just 43, a 10-fold reduction as compared with full FOV imaging (Table 5). The total cost consequence of nodules identified on limited FOV was $15,227.25. This equates to an extra $6.14 for every CTCA performed, a saving of $57.48 per scan.

Discussion

This study is the first to characterise incidental pulmonary nodules in an Australian population undertaking CTCA. We show a prevalence of pulmonary nodules of 14% with no significant difference when stratified for sex or smoking status. The nodules were predominantly <6 mm, with a lower lobe predominance. Based on Fleischner criteria we also demonstrate a projected additional conservative cost of $63.62 per patient for follow-up CT imaging, which is approximately 10% of the schedule fee for CTCA in Australia [17] and that may significantly alter the cost-effectiveness of

Table 4 Nodule Characteristics and required scans stratified on smoking status and lobar position. An upper lobe position would suggest a higher likelihood of malignancy so warrants greater follow-up, as per 2017 Fleischner guidelines.

		Nodule size*	Positive scans	Total scans & clinic review	Radiology cost	Clinic review cost	Total cost
Ever-Smokers (n)	Upper Lobe	<6 mm	18	36	$10,633.50	$2,375.30	
		6–8 mm	5	15	$4,207.50	$1,027.10	
		>8 mm	6	18	$5,049.00	$1,219.70	
	Lower lobe	<6 mm	79	158	$46,669.25	$10,207.70	
		6–8 mm	22	66	$18,513.00	$4,301.30	
		>8 mm	11	33	$9,256.50	$2,182.70	
	Total		141	326	$94,329	$21,313.80	$115,642.55
Never-smokers (n)	Upper Lobe	<6 mm	21	0	$0.00	$0.00	
		6–8 mm	4	12	$3,366.00	$834.50	
		>8 mm	3	9	$2,524.50	$641.90	
	Lower lobe	<6 mm	135	0	$0.00	$64.10	
		6–8 mm	25	50	$14,768.75	$3,274.10	
		>8 mm	16	48	$13,464.00	$3,145.70	
	Total		204	119	$34,123	$7,960.30	$42,083.55
						Overall Cost	$157,726.10

*In the case of multiple nodules this refers to the largest or highest risk nodule.

Table 5 Cost comparison Full FOV vs Limited FOV.

		Nodule Size	Positive scans	Total scans & clinic review	Radiology cost	Clinic review cost	Total cost
Limited Field of View	Ever-Smokers	<6 mm	2	4	$1,181.50	$256.80	
		6–8 mm	4	12	$3,366.00	$834.50	
		>8 mm	2	6	$1,683.00	$449.30	
		Total	8	22	$6,230.50	$1,540.60	
	Never-Smokers	<6 mm	6	0	$0.00	$0.00	
		6–8 mm	3	6	$1,772.25	$449.30	
		>8 mm	5	15	$4,207.50	$1,027.10	
		Total	14	21	$5,979.75	$1,476.40	
	Overall		22	43	$12,210.25	$3017.00	$15,227.25
Full FOV	Overall		345	445	$128,452	$29,274.10	$157,726.10

CTCA. Previous international studies on cost-effectiveness of CTCA have not incorporated these downstream costs [6].

Not surprisingly, we identified a markedly lower rate of nodule detection on limited FOV imaging, though the extent of reduction in nodules detected is higher than suggested in previous studies. Using a limited FOV would mean that there would be a reduction in observed lung nodules by over 90%, with consequent reduction in the cost of incidentally detected nodules for CTCA of 90%. We only report incidental lung nodules in this study but numerous non-cardiac findings have been described, including pulmonary emboli, rib fractures, liver and adrenal lesions and breast and oesophageal cancer [13,20]. The incidence of these is far lower than pulmonary nodules, and the clinical value of these findings and the cost consequences are beyond the scope of this paper.

Previous international studies have estimated baseline prevalence of nodules to be around 50% in a non-screening population. While the observed prevalence of nodules among our cohort is significantly lower than this it is similar to previously published cohorts in the Australian setting, in a trauma and CT screening population [21,22]. The similar prevalence of nodules between smoking and non-smoking populations has relevance when attempting to estimate the risk of lung cancer in a given patient and represents the varied aetiologies of pulmonary nodules. As MacHaalany et al. have shown, detection of malignancy can be approximated to the background population incidence of new malignancy rather than lung nodules representing a discrete risk factor for lung cancer; if the presence of a lung nodule represented an increased risk of lung cancer the prevalence of lung nodules would be expected to be higher in smokers [23].

There are a number of reasons to avoid the detection of incidental nodules, particularly in those at low risk of lung cancer. A previous study examining non-cardiac findings in CTCA observed pulmonary nodules to be common, but that <2% of these findings were clinically significant [23]. Previous authors have proposed full-FOV CTCA to be an avenue for opportunistic screening for lung cancer, however, there are three critical factors that suggest that such a proposal is not appropriate.

Firstly, full FOV CTCA routinely fails to image upper zones of the lung, and variably misses lung bases, which at least in part explains our very low observed prevalence of UL nodules. The upper lobes represent the highest risk area for lung cancer [24] and failure to image this area of lung markedly compromises the effectiveness of this as a screening tool.

Secondly, patients are selected for CTCA on broad-ranging characteristics that contribute to cardiovascular risk, not all of which affect risk for lung cancer. In our cohort, 60% of the patients were never-smokers and therefore at low risk for lung cancer. Our finding that pulmonary nodules are observed predominantly in patients excluded by NLST criteria provides strong cause for caution. It is recognised that CT screening of low risk patients for lung cancer may result in net harm, largely as a result of the high false-positive rate observed in multiple studies. In the NLST trial, 96% of CT-identified lesions were benign, and 25% of invasive procedures were performed for benign disease [19]. Our findings are consistent with other published Australian reports [21] noting a similar incidence of nodules among ever- and never-smokers, strongly suggesting that the false-positive rate is likely to be significantly higher again in a low risk group. Use of validated lung cancer risk calculators have demonstrated the likelihood of net harm of low dose computed tomography (LDCT) screening for lung cancer to be high in patients at low risk for lung cancer [25]. Cost effectiveness of screening is also very strongly correlated with lung cancer risk [19,26], suggesting that, in an unselected group of patients undergoing CTCA, identification of incidental nodules will neither benefit the patient, nor be cost-effective.

Finally, there is a significant potential effect on quality of life due to false positive findings. The effect of the discovery of pulmonary nodules on quality of life has been best studied in the context of screening, with data from a number of trials including a meta-analysis suggesting a significant though temporary impact on disease specific quality of life and distress measures [27–30]. An analysis from a subset of the National Lung Screening Trial (NLST) on the other hand showed no adverse effect on anxiety or Health Related Quality of Life (HRQoL) [31], albeit with rather blunt measures.

Unfortunately, the same cannot be said for the incidental finding of a nodule outside of organised screening programs. Whilst published literature is sparse, what exists would suggest sometimes severe distress associated with the presence of a nodule and associated follow-up [32]. This is especially pertinent in the context of our findings showing nodules detected may be financially burdensome, in the context of very low (<1%) rates of malignancy [13,33]. There is also clear evidence of psychological harm resulting from identification of incidental nodules that is much more difficult to account for in cost analyses but nonetheless constitutes net harm [34] to patients in whom nodules are identified.

An alternate argument is there is no ''cost'' to reconstructing the lung fields as the patient has already been exposed to the radiation, that physicians have an obligation to look at structures irradiated [12] and that the imaging outside of the heart is a strength of the technique [35]. Proponents of reconstructing a Full FOV draw an analogy to reporting of plain radiography of the chest [10], suggesting that one would never ignore non-cardiac structures in this case, where important information may be gained. There are also substantive potential legal implications of missing significant findings [12]. Similarly, some authors have argued that a costing cannot be reasonably placed on finding lung cancer at a curable stage. Or to phrase it another way, what cost saving justifies a missed cancer?

There is also another approach, and one that forms a crucial part of lung cancer screening, that of shared decision-making [29]. It would be a reasonable approach to include an informed discussion of the implications of incidental findings with any patient undergoing a CTCA. This must include an explanation that techniques exist to reduce findings outside the heart, but that this may mean missing something significant, even if that risk is extremely small. The patient may then share in the decision as to whether to limit the field-of-view or not.

Limitations

This is a retrospective review of a prospectively maintained database, with limitations inherent in this methodology. However, the cohort is of significant size and sampled consecutive patients. This suggests that findings of nodule prevalence and characteristics are highly likely to be representative of CTCA cohorts among our, and other, populations.

We have not included more invasive testing, nor accounted for the development of new nodules on serial imaging in our economic assumptions. Clinical follow-up on our cohort is incomplete and we are unable to report the number of subsequent invasive procedures, nor the prevalence of malignancy, both of which might impact more detailed Markov modelling of cost-effectiveness of CTCA. However, previous studies of lung cancer prevalence in CTCA have demonstrated cancer rates in an unselected population of 0.4% [13]. More complex models should also include measures of disutility [34] in examination of cost-effectiveness.

Conclusions

Indeterminate pulmonary nodules are a common incidental finding on CTCA and prevalence appears to be independent of smoking status. The majority of the nodules are small with only a minority of imaged nodules identified in the partially imaged upper lobes, where risk of lung cancer is highest. These incidental pulmonary nodules present a significant cost burden. Use of Limited FOV markedly reduces the number of incidental nodules identified, and consequently the cost burden of CTCA, but this has to be balanced against the ethical and medico-legal issues inherent in not reconstructing the entire lung fields.

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