



# Real-world first round results from a charity lung cancer screening program in East Asia

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**Background:** Screening with low-dose computed tomography (LDCT) has been proven to potentially reduce the rate of mortality of lung cancer. Lack of real-world data outside of protocolized trials has been cited as an impediment to its more widespread implementation, especially in Asia. This report aims to provide such real-world data.

**Methods:** A single round of LDCT was provided through a community-based charity program in Hong Kong, China to asymptomatic adults with a family history of lung cancer and/or smoking history. Anonymized data from this program were analyzed.

**Results:** LDCT was performed for 99 participants, including 98 (99%) who had one or more family members with history of lung cancer, and 70 (71%) who were never-smokers. After a single round of screening, a positive LDCT was noted in 47 participants (47%). A sister with a history of lung cancer (28% *vs.* 8%,  $P=0.01$ ) and a multiplex family (MF) (47% *vs.* 23%,  $P=0.02$ ) were factors associated with a positive LDCT. After a median period of 10 months (range, 5–16 months) following LDCT, lung cancer (all adenocarcinoma) was diagnosed as a direct consequence of positive LDCT findings in six participants (6%), of whom four had stage I disease and five received surgery with curative intent. In the 47 participants with a positive LDCT, having a sister with a history of lung cancer was associated with an increased risk of lung cancer (relative risk =5.23; 95% confidence interval: 1.09–25.21). Detected lesions categorized as Lung Imaging Reporting and Data System (Lung-RADS) 3 or above (odds ratio =12.08; 95% confidence interval: 1.27–114.64) or deemed by an experienced specialist to be suspicious (odds ratio =63.33; 95% confidence interval: 5.48–732.29) were significantly more likely to turn out to be a lung cancer.

**Conclusions:** This real-world data demonstrates that a single round of LDCT screening at a community level in East Asia can detect potentially curable lung cancer at a rate comparable to those reported by protocolized trials. When considering future LDCT screening programs in East Asia, a family history of lung cancer may be a key factor indicating a person for screening, and how features of a LDCT-detected lesion should trigger further intervention warrant further definition.

**Keywords:** Low-dose computed tomography (LDCT); lung cancer; real world; screening

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## Introduction

Screening for lung cancer using low-dose computed tomography (LDCT) has emerged in recent years as potentially the most powerful means of reducing the mortality of this disease (1-3). The American National Lung Screening Trial (NLST), the European NELSON trial, and the TALENT study from Taiwan, China demonstrated that LDCT was an effective instrument to detect early-stage lung cancer, and significantly reduce lung cancer mortality rates (2-4).

However, the implementation of LDCT screening worldwide has encountered resistance (5,6). This often stems from perceived insufficiencies in terms of: real-world data outside of clinical trials; global consensus over risk factors identifying eligibility for screening (including regional variations); understanding of how many rounds of screening are necessary to yield meaningful results; observation of how screening-detected lesions are managed in real-world healthcare systems; and so on. In particular, it is now recognized that clinical trials investigate only a small selected segment of the population in a controlled (somewhat artificial) environment (7,8). In the absence of more real-world data, there have thus been calls for caution when appreciating the mortality reductions reported in the above screening trials, as these were obtained in highly selected cohorts, following specific protocols, predominantly at large academic institutions (9).

### Highlight box

#### Key findings

- In a charity program to promote lung cancer screening in Hong Kong, findings from a single round of low-dose computed tomography (LDCT) led to a diagnosis of lung cancer in 6% of participants.

#### What is known and what is new?

- Previous clinical trials with regimented study protocols selected persons with a history of smoking for screening, detecting lung cancer in 0.9–1.1% of them.
- In this reported cohort undergoing screening outside of a research trial setting, a family history of lung cancer was the key risk factor indicating eligibility for lung cancer rather than smoking.

#### What is the implication, and what should change now?

- This real-world data demonstrates that LDCT screening at a community level in East Asia is effective for detecting lung cancer. However, eligibility criteria for screening may require reconsideration compared to those in previous protocolized trials.

This report aims to analyze the data collected from the first round of a community-based, charity LDCT lung cancer screening program in Hong Kong, China to understand if the efficacy of LDCT lung cancer screening seen in international trials can be replicated in a real-world setting. We present this article in accordance with the STROBE reporting checklist (available at <https://jtd.amegroups.com/article/view/10.21037/jtd-24-411/rc>).

## Methods

### *Patients and management*

From December 2021 to November 2022, a charity foundation in Hong Kong, China offered a single round of free LDCT screening once to 100 eligible applicants from the public on a ‘first come, first served’ basis. This quota of 100 free LDCT scans was made available by a charitable donation to the Foundation and this set the limit of participants. The aim of this charity LDCT lung cancer screening program was to promote awareness of the need and nature of such screening amongst the general population of Hong Kong, China. The intention was that if the 100 participants were receptive to the potential benefits and the process of undergoing LDCT, they might help spread this awareness by word-of-mouth to friends and family members. Calls for participants were made via press releases in the local print media. Participation in the screening program was entirely voluntary and no incentives were offered to participants other than the LDCT. The eligibility criteria were:

- ❖ Asymptomatic;
- ❖ Age 40 years or older;
- ❖ Smoking history (ever-smoker) and/or family history of lung cancer;
- ❖ No history of previous malignant disease within the past 10 years;
- ❖ Able to provide informed consent.

All persons responding to the calls for participants were checked for eligibility according to the above criteria by a specialist lung cancer physician with over 20 years’ experience in treating lung cancer offering pro bono services. Those found eligible were referred to receive LDCT at one of a list of private diagnostic imaging centers offering discounted rates as part of the charity program. Each LDCT scan was assessed by the reporting radiologist at the private diagnostic imaging center, and also by the above specialist lung cancer physician. A LDCT scan was

defined as positive if both the reporting radiologist and the specialist noted one or more discrete non-calcified lung nodular lesion. Each lesion was classified as a solid nodule, part-solid nodule, or ground-glass opacity (GGO). The Lung-RADS™ Version 2022 Assessment was further applied to classify lesions found (10). The specialist gave a comment on whether any identified lesion appeared suspicious of being a malignant neoplasm, and individually advised each screened participant on whether or not further medical attention was warranted. As the charity was not a medical facility, any such further medical management was undertaken by the public health service of Hong Kong, China.

The charity subsequently maintained phone contact with all screening program participants. Participants were invited to report (on a voluntary, non-incentivized basis) to the charity if they were subsequently found to have lung cancer as a result of medical investigations arising from the screening program LDCT.

#### *Data collection*

This is a retrospective observational report analyzing previously collected anonymized data from a single cohort. It is emphasized that this project originated entirely from a charitable project to promote awareness of screening, and was not designed from the outset as a prospective clinical study. As such, there was no prior planning with regards estimating cohort sizes and other elements common to prospective clinical trials.

The data collected by the charity during the screening program were anonymized prior to analysis. All participants were contacted by the charity and all confirmed their consent for their anonymized data to be used in this study. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013), and was approved by the Ethics Committee of the Hong Kong Doctors Union (HKDU REC No. 2023/02).

#### *Statistical analysis*

The primary end point was the rate of detection of any biopsy-confirmed lung cancer. Fisher's exact test or two-sample *t*-test was used to test the difference between groups for categorical data or continuous data, respectively. All statistical tests were performed using MedCalc® Statistical Software version 22.017 (MedCalc Software Ltd., Ostend, Belgium).

## **Results**

### *Participants' demographic and clinical characteristics*

During the study period, one LDCT scan was arranged for each of the 100 participants meeting the eligibility criteria. One participant withdrew before the LDCT was performed, and anonymized data for the 99 participants who received LDCT were analyzed. A summary of the demographic and clinical characteristics is shown in *Table 1*. A history of lung cancer in one or more family members was reported by 98 participants (99%). There were 34 participants (34%) who came from a multiplex family (MF), defined as a family with two or more family members with history of lung cancer. There were 29 participants (29%) with a history of smoking, including 16 current active smokers (16%), and 13 ex-smokers (13%). There were 45 participants (45%) with a significant past medical history, defined as having had major surgery for non-traumatic pathology or currently using medical therapy for any pathology.

### *LDCT findings*

In this single round of screening, a positive LDCT was noted in 47 participants (47%). There were 24 participants (24%) who had multiple (more than one) lesion found on LDCT. In total, at least one solid nodule, part-solid nodule, or GGO was found in 36 (36%), 2 (2%), and 13 (13%) participants respectively. Having a sister who had lung cancer or a MF were associated with a positive LDCT (*Table 1*).

Of the 47 participants with positive LDCT, the largest lesion being Lung Imaging Reporting and Data System (Lung-RADS) category 3 occurred in 12 participants (12%) and Lung-RADS category 4 in 5 participants (5%).

The experienced lung cancer specialist commented that the identified lesions in 8 participants (8%) were suspicious of being a malignant neoplasm, and advised intervention. These eight lesions included Lung-RADS category 2, 3, and 4 lesions in two, two, and four participants respectively. When correlating the specialist's comment of a suspicious lesion with a Lung-RADS category of 3 or more, the inter-observer agreement test Weighted Kappa value was 0.40, indicating fair agreement only.

### *Lung cancer incidence and outcomes*

Telephone interviews were contacted for all 99 participants who received LDCT at a median period of 10 months

**Table 1** Characteristics of participants in lung cancer screening charity program using LDCT

Parameters	Entire cohort (n=99)	Positive CT findings (n=47)	P value (positive vs. no positive CT findings)	Cancer diagnosed (n=6)	P value (cancer vs. no cancer diagnosed)
Male	53 [54]	26 [55]	>0.99	5 [83]	0.21
Age (years)	57.6±6.9	58.8±6.4	0.09	56.2±4.1	0.43
Smoking history	29 [29]	18 [38]	0.12	3 [50]	0.35
Significant PMH	45 [45]	22 [47]	0.84	3 [50]	>0.99
History of TB	7 [7]	3 [6]	>0.99	0 [0]	>0.99
Relative with history of lung cancer					
Father	54 [55]	23 [49]	0.32	1 [17]	0.09
Mother	33 [33]	17 [36]	0.67	1 [17]	0.66
Brother	17 [17]	11 [23]	0.18	2 [33]	0.27
Sister	17 [17]	13 [28]	0.01*	4 [67]	0.01*
Other	11 [11]	6 [13]	0.75	1 [17]	0.52
MF	34 [34]	22 [47]	0.02*	4 [67]	0.18

Data are presented as n [%] or mean ± SD. \*, P<0.05. LDCT, low-dose computed tomography; CT, computed tomography; PMH, past medical history; TB, tuberculosis; MF, multiplex family; SD, standard deviation.

(range, 5–16 months) after the LDCT was performed. After this single round of LDCT screening, a biopsy-confirmed diagnosis of lung cancer was made in six participants (6%). In all 6 participants, the diagnosis was a direct consequence of investigations pursued for positive LDCT findings from the screening program. In all six, the histological type was adenocarcinoma. The characteristics of these six participants are summarized in *Tables 1,2*.

One patient had stage IV disease by the time of diagnosis and received palliative therapy only. The other five participants diagnosed with lung cancer (83%) received surgery with curative intent. Four of those with lung cancer (67%) had stage I disease. It is noted that in the two participants with stage III and stage IV disease respectively, there was a substantial time interval between the LDCT being done and the diagnosis being eventually obtained.

*Table 3* summarizes the analyses of risk factors for lung cancer amongst the 47 participants with positive LDCT. Having a sister with a history of lung cancer was the only identified risk factor predictive of a positive LDCT lesion turning out to be a lung cancer (relative risk =5.23; 95% confidence interval: 1.09–25.21; P=0.04). Both a Lung-RADS category of 3 or above and a specialist's comment or

a lesion being suspicious of a malignancy were significantly predictive of a positive LDCT lesion turning out to be a lung cancer. Five (83%) of the 6 patients with lung cancer had a lesion of Lung-RADS category of 3 or above, compared with 12 (29%) in the 41 patients with positive LDCT but no cancer (P=0.03). Five (83%) of the 6 patients with lung cancer were commented by the specialist to have a suspicious lesion on LDCT, compared with 3 (7.3%) in the 41 patients with positive LDCT but no cancer (P<0.01). It is noted that one patient with lung cancer had a lesion of Lung-RADS category of 3 or above but no comment of suspicion by the specialist, and another one patient with lung cancer had a comment of suspicion by the specialist but the Lung-RADS category was only 2.

In addition to the above six participants who were found to have lung cancer, a seventh participant who did not have positive findings on the first round of LDCT was subsequently found to have stage I lung cancer. This was a 71-year-old male smoker whose daughter had lung cancer. Because of his raised awareness of the importance of screening after the charity-provided first round of LDCT, he later sought out a follow-up LDCT at an undisclosed time later. This follow-up scan detected the lung cancer and

**Table 2** Characteristics of participants diagnosed with lung cancer after positive findings of single round of screening

Patient	Number of lesions	Size of largest lesion	Lung-RADS category	Specialist's Comment	Lung cancer stage at diagnosis	Treatment	Remarks
1	1× GGO	4 mm GGO	2	Suspicious—advise intervention	I	Surgery	–
2	1× SN	8 mm solid nodule	4A	Suspicious—advise intervention	IV	Non-surgical	Delayed presentation to and workup at managing hospital
3	1× SN, 1× GGO	7 mm solid nodule	3	Advise CT at 3–6 months	I	Surgery	–
4	3× SN	15 mm solid nodule	4B	Suspicious—advise intervention	III	Surgery + adjuvant therapy	4-month interval from screening to treatment at managing hospital
5	1× PSN	15 mm part-solid nodule	4A	Suspicious—advise intervention	I	Surgery	–
6	5× SN	4 mm solid nodule	3	Suspicious—advise intervention	I	Surgery	2-month interval between screening and biopsy at managing hospital

Lung-RADS, Lung Imaging Reporting and Data System; GGO, ground-glass opacity; SN, solid nodule; CT, computed tomography; PSN, part-solid nodule.

he received surgery with curative intent for this.

## Discussion

After a single round of a community-based, charity LDCT lung cancer screening program in Hong Kong, China, 6% of the participants were found to have lung cancer as a direct consequence of findings from screening, and 83% of those received surgery with curative intent. In comparison, the American NLST detected 1,060 lung cancers (4%) among 26,722 participants who had LDCT after 3 rounds of screening, with 520 cancers (49%) being in stage I (2). The European NELSON trial detected 203 lung cancers (3%) among 6,583 male participants as a direct result of four rounds of LDCT screening, with 119 cancers (57%) being in stage I (3). The TALENT study from Taiwan, China detected 311 lung cancers (3%) among 12,011 participants who had LDCT after a single round of screening, with 300 cancers (96%) being in stage 0 or I (4). These results suggest that LDCT can be potentially effective in a real-world setting outside of clinical trials or health authority-provided programs.

Rates of diagnosis of lung cancer after only the first round of screening in the NLST and NELSON trials were 1.1% and 0.9% respectively (2,3). Single round detection rates of 0.5–1.5% have previously been reported in studies

from the USA and China (11–13). The results of this study reaffirm the TALENT study finding that even a single round of LDCT screening can be potentially even more effective than previously reported. In our screening program, it is worth noting that a seventh case of lung cancer was detected when the participant pursued a follow-up LDCT after the free charity-provided first LDCT was negative. This suggests that providing even a single round of LDCT can be effective in promoting awareness among the public, and hence generating potentially lasting health education benefits. This may have implications for future LDCT screening programs when considering the number of rounds that could be funded.

Another key consideration for LDCT screening programs is the identification of a “high risk” population that should be offered screening (6,9). Hitherto, American guidelines—such as those of the American Cancer Society (ACS)—focus on age (typically 50 years or older) and a long smoking history (typically  $\geq 20$  pack-year smoking history) as the primary selection criteria, mainly based on data for American populations (14,15). However, recent evidence from China suggests that if such criteria were applied in an East Asian population, a majority of lung cancer cases would be missed by screening (16). The TALENT study targeted non-smoking persons in East Asia and found equal or greater lung cancer detection rates than Western

**Table 3** Correlation of potential risk factors with diagnosis of lung cancer in participants with positive findings after a single round of screening

Parameters	No cancer (n=41)	Cancer diagnosed (n=6)	RR/OR (95% CI)	P value
Male	21 [51]	5 [83]	RR: 4.04 (0.51–31.96)	0.19
Age (years)	59.3±6.6	56.2±4.1		0.15
Smoking history	15 [37]	3 [50]	RR: 1.61 (0.36–7.13)	0.53
Significant PMH	19 [46]	3 [50]	RR: 1.14 (0.26–5.06)	0.87
History of TB	3 [7]	0 [0]	RR: 0.87 (0.06–12.73)	0.92
Relative with history of lung cancer				
Father	22 [57]	1 [17]	RR: 0.21 (0.03–1.65)	0.14
Mother	16 [39]	1 [17]	RR: 0.35 (0.04–2.78)	0.32
Brother	9 [22]	2 [33]	RR: 1.64 (0.34–7.77)	0.54
Sister	9 [22]	4 [67]	RR: 5.23 (1.09–25.21)	0.04*
Other	5 [12]	1 [17]	RR: 1.37 (0.19–9.79)	0.76
MF	18 [44]	4 [67]	RR: 2.27 (0.46–11.23)	0.31
Findings on CT				
Solid nodule	32 [78]	4 [67]	RR: 0.61 (0.13–2.90)	0.54
Part-solid nodule	1 [2]	1 [17]	RR: 4.50 (0.90–22.59)	0.07
GGO	12 [29]	2 [33]	RR: 1.18 (0.24–5.71)	0.84
Multiple lesions	22 [54]	2 [33]	RR: 0.48 (0.10–2.37)	0.37
Largest lesion size (mm)	4.4±2.6	8.8±5.0		0.08
Lung-RADS category ≥3	12 [29]	5 [83]	OR: 12.08 (1.27–114.64)	0.03*
Deemed suspicious by specialist	3 [7]	5 [83]	OR: 63.33 (5.48–732.29)	<0.01*

Data are presented as n [%] or mean ± SD. \*, P<0.05. MF is defined as a family with two or more family members with history of lung cancer. Lung-RADS category is assessed using v2022 (available at <https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Lung-Rads>). RR, relative risk; OR, odds ratio; CI, confidence interval; PMH, past medical history; TB, tuberculosis; MF, multiplex family; CT, computed tomography; GGO, ground-glass opacity; Lung-RADS, Lung Imaging Reporting and Data System; SD, standard deviation.

screening studies (4). This reinforces the view that smoking should perhaps not have such a major role in Asia (5,17). Instead, a follow-up to the TALENT study demonstrated that a family history of lung cancer (especially maternal relative history) may be an even stronger risk factor in East Asian non-smokers (18). Our current screening program included a population with 99% of participants having a family history of lung cancer and only 29% who were current- or ex-smokers. The lung cancer detection rate of 6% in our screening program tends to support the view that family history may be a more effective selection criterion for screening than smoking. It should be noted that if the ACS guidelines had been applied in our screening program, three of the six cases of lung cancer (50%) would have been

denied screening and the diagnosis missed because those participants were never-smokers.

Another concern with LDCT screening is the issue of potential “over-diagnosis” (19–21). Many screening-detected lung lesions are not lung cancer, and hence there is a real concern that if each such lesion was investigated, this would lead to “unnecessary” interventions and possible morbidity for participants (21). There have thus been a number of proposals on how to identify “high risk” lesions only for intervention. These have included: use of the Lung-RADS categorization of lesions; volumetric or AI analysis of lesions; supplementing analysis with liquid biopsy molecular testing; and others (6,10,22–24). Most of these are still experimental or not yet mature enough

for clinical use, but the lung-RADS system is gaining widespread acceptance (10). In our screening program, a Lung-RADS category of 3 or higher was associated with an eventual diagnosis of lung cancer. However, only five of the 17 participants (29%) with a Lung-RADS 3 or higher lesion were found to have lung cancer, suggesting that this method to identify “high risk” lesions for intervention may still have suboptimal specificity. Instead, the identification of a lesion suspicious of malignancy given by an experienced lung cancer specialist appeared to be even better correlated with an eventual diagnosis of lung cancer. Lung cancer was found in five of the eight participants (63%) noted to have a suspicious lesion by the specialist. It is recognized that the expertise of an individual specialist cannot be used as the basis to formulate protocols for managing screening-detected lesions. Nonetheless, the results of our screening program suggest that it is potentially possible to find methods of identifying lesions for intervention that are more reliable than the current Lung-RADS system.

Once a lesion is identified for intervention, the interval from detection to diagnosis or to treatment is critical (25,26). In our screening program, one lung cancer case had stage IV disease at the time of diagnosis, and another had stage III disease. In both cases, a significant interval (over 2 months) was noted between the detection on screening and the management by the public health service. Although it is not possible to attribute the late-stage diagnoses to any delay, it is nevertheless preferable to shorten the interval. Our screening program results suggest that future screening programs should consider incorporating a mechanism for expeditious and automatic referral from the screening unit to the intervention unit. The potential of screening cannot be fully realized unless a pathway exists to efficiently manage suspicious lesions that are detected.

This report of our screening program has limitations. As this was not a formal trial or clinical study, there was no mechanism for follow-up of all participants. A diagnosis of lung cancer could only be checked by a telephone interview after a median of 10 months’ interval after the LDCT, so this was only a cross-sectional observation with unequal follow-up of all participants. As a result, the subsequent outcomes of those 93 participants not reporting lung cancer at the time of telephone interview and data analysis are unknown. Those 93 participants included some with lesions categorized as Lung-RADS 3 or greater or noted to be suspicious by the lung cancer specialist. As no true negative figure is available, accuracy results for LDCT cannot be computed. Also, because of the lack of follow-up beyond the

charity’s provision of a single round of LDCT, our results do not provide any insight into the impact of LDCT on lung cancer mortality or into the role of subsequent rounds of LDCT screening. It is also acknowledged that the cohort in this charity screening program is small compared to the studied cohorts in previous major trials of LDCT screening. The small numbers involved preclude a more thorough statistical analysis of the risk factors for positive LDCT findings or diagnosis of lung cancer. However, the data from our charity screening program are nevertheless a rare and important representation of LDCT screening in a real-world community outside of the highly-selected cohorts in an academic trial or government registry. As such, even a small cohort should add real-world value for planning of future screening programs.

## Conclusions

The experience of this community-based charity lung cancer screening project demonstrates that first round LDCT screening can provide real-world lung cancer detection results equivalent to or better than those achieved through highly selective and protocolized clinical studies. The results also suggest that different selection criteria for screening may exist in different populations (such as family history in East Asian populations), and that an optimal management pathway for screening-detected lesions remains to be defined.

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## Footnote

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*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All participants were contacted by the charity and all confirmed their consent for their anonymized data to be used in this study. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and was approved by the Ethics Committee of the Hong Kong Doctors Union (HKDU REC No. 2023/02).

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