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Community-based lung cancer screening with low-dose CT in China: Results of the baseline screening

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ABSTRACT

Objectives: To investigate whether low-dose computed tomography (LDCT) screening is capable of enhancing the detection rate of early-stage lung cancer in high-risk population of China with both smoking and non-smoking related factors.

Methods: From 2013–2014, eligible participants with high-risk factors of lung cancer were randomly assigned to a screening group or a control group with questionnaire inquiries. Any non-calcified nodules or masses with longest diameters of ≥4 mm identified on LDCT images were considered as positive.

Results: A total of 6717 eligible participants were randomly enrolled to a study group (3550 to LDCT screening and 3167 to standard care). 3512 participants (98.9%) underwent LDCT screening, and 3145 participants (99.3%) received questionnaire inquiries. A positive screening result was observed in 804 participants (22.9%). In the two-year follow-up period, lung cancer was detected in 51 participants (1.5%) in the LDCT group versus 10 (0.3%) in the control group (stage I: 48 vs 2; stage II to IV or limited stage: 3 vs 8), respectively. Early-stage lung cancer was found in 94.1% vs 20%, respectively.

Conclusions: Compared to usual care, LDCT led to a 74.1% increase in detecting early-stage lung cancer. This study provides insights about the non-smoking related risk factors of lung cancer in the Chinese population.

1.0. Introduction

In China, lung cancer is now the most common cancer and the first cause of cancer mortality. An estimated 704,800 new lung cancer cases and 569,400 lung cancer deaths occurred in 2012, accounting for about 19.7% of total cancer diagnoses and 26.0% of total cancer deaths [1]. Most new lung cancer cases and cancer deaths occur in the age range from 45 to 74 years. In addition, an upward trend in age-standardized incidence rates was observed for lung cancers in female, compared to a stable trend in male [2].

Currently, no definitive biomarker or genetic factor has been identified for the prediction or the early diagnosis of lung cancer. Low-dose computed tomography (LDCT) has been applied as a promising approach for lung cancer screening according to the National Lung Cancer Screening Trial (NLST) [3]. LDCT showed better performance for the detection of early-stage lung cancer than chest X-ray and demonstrated a significant reduction in lung cancer-related mortality mainly due to detection at earlier stages when applied to a high-risk population, which is often defined by age and smoking.

An estimated 15% of male lung cancer and 53% of female lung cancer (25% of all cases) are not attributable to tobacco use [4]. Epidemiology studies identified that lung cancer in never smokers occurs more frequently in female than in male. The proportion of female lung cancer is particularly high in China despite a lower prevalence of smoking [5]. Striking differences in the epidemiological, environmental exposures and molecular characteristics arising in the Chinese

Abbreviations: LDCT, Low-dose computed tomography; COF, Cooking oil fumes; NLST, The National Lung Screening Trial; NELSON, The Dutch-Belgian randomized lung cancer screening trial (Nederlands-Leuvens Longkanker Screenings Onderzoek); ELCAP, The early lung cancer action Project; VDT, Volume-doubling time

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population have not been clearly identified yet. This strongly highlights the need for additional research in smoking as well as in non-smoking related risk factors for lung cancer in China. Unfortunately, no reliable information for selecting the screening population in China is currently available.

The paper describes the baseline screening results of trial conducted as a randomized controlled study in a Chinese population with a high risk of lung cancer.

2.0. Participants and methods

2.1. Study design

This study is a prospective randomized controlled trial. It was approved by the Ethics Committee of Shanghai Chest Hospital, Shanghai Jiao Tong University, Shanghai, China (No. KS1407). Written informed consent was obtained from every patient participating in this research when they were enrolled. The primary aim of this study is to evaluate the efficiency of LDCT in lung cancer detection in asymptomatic high-risk population. The second aim is to evaluate the impact of LDCT on lung cancer-specific mortality.

2.2. Participants

From November 2013 to November 2014, subjects were recruited through general practitioners and advertising leaflets in 6 communities (2 housing estates in each community were randomly selected, 6–8 residential buildings were randomly selected at each housing estate, ≥500 residents in these 6–8 buildings were invited to fill in a home-based questionnaire). We included asymptomatic residents, 45–70 years of age, showing at least one high-risk factor: 1) current or former smokers who had a history of at least 20 pack-years of cigarette smoking, and for former smokers, no more than 15 years since quitting; 2) cancer history of any kind in close family members; 3) cancer history of any kind for the participant; 4) occupational exposure to carcinogenic agents (asbestos, dust or radiation); 5) long history of passive smoking (> 2 h every day in homes or indoor workplaces for at least ten years); and/or 6) long-term exposure to cooking oil fumes (cooking history of stir frying, frying or deep frying > 50 dish-years). Individuals excluded from the study had previously received a diagnosis of lung cancer, had a performance status (PS) > 2, had a CT scan of chest within the last 12 months or had a diagnosis of any other cancer (including lung cancer) within the past 5 years.

All participants signed the informed consent on a voluntary basis. Participants were assigned to undergo LDCT screening or standard care by 1:1 balanced randomization with a total of 12 blocks (2 blocks in each community) from December 2013 till December 2014. Demographic data and a medical history were recorded at the time of enrollment. Participants with positive screening findings were asked to provide blood for future biomarker research (10 ml).

2.3. Screening

Participants in the LDCT group were invited to receive thoracic LDCT every two years for three rounds. Spiral CT images were obtained using a 64-detector CT row scanner (Brilliance, Philips, USA) with a low-dose setting (140kvp, 40 mA) and were reconstructed in overlapping contiguous 5-mm increments, pitch 1.25.

LDCT data were stored in our imaging archive and communication system (Kingstar Winning, Shanghai, China). All screening images have been rated by two senior radiologists and three experienced clinicians using a 2-megapixel grey scale monitor (JUSHA-M21, Nanjing, China) at lung windows (width 1450 HU, level -520HU) and mediastinal windows (width 350 HU, level 40HU). Measurements have been taken from full screen or with magnification.

Any non-calcified nodules or masses with longest diameters of ≥4 mm identified on LDCT images were considered as positive. For any positive pulmonary nodule, its size and specific radiological feature (shape, margin and attenuation) was recorded. Within 4 weeks screening results have been communicated with the participant by the responsible community health center. If none of the noncalcified nodules identified met the study criteria for a positive result or if the test was negative, CT was repeated 24 months after the baseline CT.

2.4. Follow-up

The management of positive screening results was carried out according to the recommendation of the NCCN clinical practice guidelines in oncology: lung cancer screening (2014.V1) [6]. Health and mortality outcomes of all participants in both study groups were followed for at least five years via Shanghai Municipal Centers for Disease Control and Prevention. For participants with a diagnosis of lung cancer, all related diagnostic procedures, histologic type, tumor stage, initial treatment and postoperative treatment (not reported here) were collected by certified medical record. Histopathological and tumor stage was assessed using the 2015 World Health Organization (WHO) classification of tumors for the lung, pleura, thymus, and heart [7] and the eighth edition of the TNM Classification for Lung Cancer [8]. Early stage lung cancers were defined as stage 1.

2.5. Statistical analysis

Differences were compared between the LDCT and the control group in terms of demographic features, high-risk factors and final diagnosis using independent sample *t*-tests or χ^2 tests, as appropriate. The level of statistical differences was set at 0.05. As statistical tool STATA (version 14.0; Stata Corporation, College Station, TX) was used.

3.0. Results

A total of 6717 participants were recruited, of which 8 participants were excluded because they had lung cancer before enrollment, 50 declined to participate, and 2 underwent incorrect screening, respectively. Of the remaining 6657 participants, 3512 (52.8%) were randomized to screening by LDCT, and 3145 (47.2%) were assigned to the control group. Fig. 1 describes the inclusion process in detail.

LDCT was performed in 98.9% (3512/3550) of the participants in the LDCT group. Women represented 53.2% of the enrolled sample. The mean age at enrollment was 59.8 ± 5.8 years. The proportion of current smokers was 21.5%, with a higher proportion in male. No statistically significant differences in age, gender, smoking status, exposure history to COF and carcinogens, personal or family cancer history for the probands, respectively, were observed between the LDCT and the control group (Table 1).

Overall 804 (22.9%) participants showed non-calcified nodules ≥4 mm on LDCT images: with suspicious nodules of sizes < 5 mm in 325 subjects, ≥5–6 mm in 338 subjects, > 6–10 mm in 74 subjects, > 10–20 mm in 45 subjects, > 20–30 mm in 18 subjects and > 30 mm in 4 subjects (Table 2).

After two-year follow up, one participant with multiple pulmonary nodules was diagnosed as metastasized from prostatic cancer. In 37 participants with positive rated

nodules size after anti-inflammatory decreased or the nodules have been considered as benign after multidisciplinary discussions. The remaining 706 patients are still under observation (Table 2). Surgical resections were performed in 60 (7.5%) of the participants with suspicious nodules, including 51 (6.3%) who had malignant lesions, 4 (6.7%) had adenocarcinomas in situ and 5 (0.6%) who had benign lesions (3 with hemtomas, 1 with pulmonary alveolar proteinosis and 1 with chronic inflammation). There was no operative mortality or any death from surgical resection within 90 days. Thus, in total, detected lung cancers were found in 51 of the 3512 participants (1.5%) versus 10

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