ORIGINAL ARTICLE

Results of an open-access lung cancer screening program with low-dose computed tomography: the Gdańsk experience

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KEY WORDS

computed tomography, early detection of cancer, lung cancer

ABSTRACT

INTRODUCTION Lung cancer screening with low-dose computed tomography (LDCT) is one of the most promising tools for reducing mortality from lung cancer.

OBJECTIVES The aim of the study was to evaluate the results of an open-access lung cancer screening program with LDCT.

PATIENTS AND METHODS In total, 8649 asymptomatic volunteers between 50 and 75 years of age with a smoking history of at least 20 pack-years underwent LDCT screening. The presence of lung nodules with a diameter of less than 5 mm required a follow-up control visit after 12 months, and with a diameter of 5 to 10 mm—after 3, 6, and 12 months. Patients with a nodule of more than 10 mm in diameter required further diagnostic workup.

RESULTS Lung nodules were detected in 4694 individuals (54%). Lung cancer was diagnosed in 107 patients (1.24%). Of 8649 participants, 300 (3.5%) were referred for further diagnostic workup, and 125 (1.5%) underwent surgical resection (81 because of malignant lesions; 44, benign lesions). Eighty-one participants (75%) underwent surgery with a curative intent, and 26 participants underwent oncological treatment. There were no perioperative deaths. The majority of surgical patients underwent lobectomy (video-assisted, in 30 patients; and open, in 38 patients). Stage I non-small cell lung cancer was detected in 64 of the surgical patients (79%).

CONCLUSIONS The detection rate of lung cancer in the screening program with low-dose computed tomography is relatively low but patients were diagnosed at a very early stage of the disease compared with standard clinical practice.

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INTRODUCTION After primary prevention strategies, lung cancer screening is probably the most promising strategy for reducing lung cancer-related mortality. Among several screening tools that have been tested, low-dose computed tomography (LDCT) appears to be the most promising.[1-3] In 2006, Henschke et al.[4] reported the results of a cohort of patients with non-small cell lung cancer (NSCLC) diagnosed using LDCT. They observed a high prevalence of stage I NSCLC, with a 10-year survival rate of 88% in patients who underwent surgical resection.[4] The favorable outcomes in the group of NSCLC patients who were diagnosed in the International Early Lung Cancer Action Program (I-ELCAP) provided an important message to all scientists involved in LDCT lung cancer screening. Since the National Lung Screening Trial demonstrated a reduction in lung cancer-related mortality greater than 20% in the LDCT-screened arm compared with that in the chest-radiography arm, the interest in this screening method has significantly increased.[5]

So far, 10 randomized and 18 observational LDCT screening studies regarding lung cancer have been published.[5,6] Although numerous questions in this field have been answered, several aspects of LDCT screening remain unclear. In this article, we present the early results of the Pilot Pomeranian Lung Cancer Screening Program in Gdańsk, Poland.

PATIENTS AND METHODS Between February 2009 and April 2011, 8649 healthy volunteers were examined using LDCT in the Pomeranian Lung Cancer Screening Program after providing informed consent. The study was approved by the institutional review board of the Medical University of Gdańsk (NKEBN/109/2009). The program was financed by a grant founded by the European Economic Area Financial Mechanism (85%) and the Marshall of the Pomeranian Voivodeship (15%). This study focused on the inhabitants of the Pomeranian region in northern Poland (2.2 million inhabitants) at high risk for developing lung cancer. Based on the Arterial Hypertension in Poland study,[7] it has been estimated that 180 000 individuals are potentially in the high-risk group as described below. The aim of the study, in addition to investigating screening using LDCT, was to educate regional medical staff (family doctors, family nurses, and radiologists) about lung cancer diagnosis, treatment, and screening to build a lung cancer diagnostic and therapeutic network in Pomerania for potential use in future studies.

Participants The program included healthy asymptomatic current or former smokers aged between 50 and 75 years with a smoking history of at least 20 pack-years. Among individuals with a family history of smoking, the minimum smoking history was 10 pack-years. The number of recruited participants was determined by the program's budget.

Recruitment methods Participants were recruited via a website and infolines during the first week and via infolines, family doctors, and nurses thereafter. Website recruitment was discontinued owing to an overwhelming interest (over 2000 registrations within the first 4 days). Participants were also recruited via television, radio, and newspaper advertisements as well as via an informational campaign involving educated family doctors and nurses.

Low-dose computed tomography LDCT was performed in 19 radiological centers in Pomerania. All radiologists were educated about the study protocol and reading LDCT scans to evaluate the features of nodules. The I-ELCAP radiological protocol was applied with regards to the equipment requirements and methodology.

Screening The screening protocol was designed for a 1-year follow-up due to the programs' time frames. Individuals were categorized into 1 of 4 groups: 1) a group with a negative LDCT result, which was excluded from further follow-up; 2) a group with nodules of less than 5 mm in size, which had 1 follow-up visit after 12 months; 3) a group with nodules between 5 and 10 mm in size, which had follow-up visits 3, 6, and 12 months after the first LDCT; and 4) a group with nodules exceeding 10 mm in size, who were referred for further diagnostic workup. The number, diameter, size, consistency, presence of air, shape, and edge pattern of nodules as well as the presence of calcification and additional findings were recorded in the form available on the program's website by each radiologist and consultant.

All positive results were reviewed by 3 consultants (2 radiologists and 1 thoracic surgeon) who decided whether further screening was needed. The results were entered into a web-based form and collected in a central database. The results were provided to participants in the radiological center in which the study was performed with detailed guidelines. All patients who were subject to screening were suggested to undergo additional LDCT screening every 12 to 15 months on their own.

The diagnostic workup in patients with nodules greater than 10 mm in size was performed in the Department of Thoracic Surgery of the Medical University of Gdańsk, and the workup consisted of spirometric tests, exertion tests, bronchoscopy or autofluorescence bronchoscopy, and fine-needle aspiration biopsy.[8,9] All patients referred for surgery underwent surgery in the same institution. The study flowchart is presented in FIGURE 1.

Additional projects A total of 1596 health care professionals (915 family doctors, 55 radiologists, and 626 family nurses) from the Pomerania region were educated about lung cancer diagnosis and treatment as well as lung cancer screening in a series of 18 training sessions.

In 3373 program participants, blood was collected for further molecular studies[10] after participants provided written informed consent.

In 724 participants, pilot cardiovascular screening was performed on the basis of the same definition of the high-risk group. In all participants, primary cardiovascular risk factors were assessed. This issue will be presented in a separate publication.

RESULTS In 8649 healthy volunteers (median age, 60.6 years) who underwent LDCT screening, 13 978 computed tomography examinations were performed. In total, 3004 of 8649 individuals (34.7%) underwent more than 1 round of LDCT screening. Men and women constituted 52% and 48% of the patient cohort, respectively. In addition, the cohort included 68% of current and 32% of former smokers who had a mean smoking history of 35 pack-years (range, 0–200 pack-years).

Lung nodules were detected in 4694 individuals (54%), most commonly as a single nodule

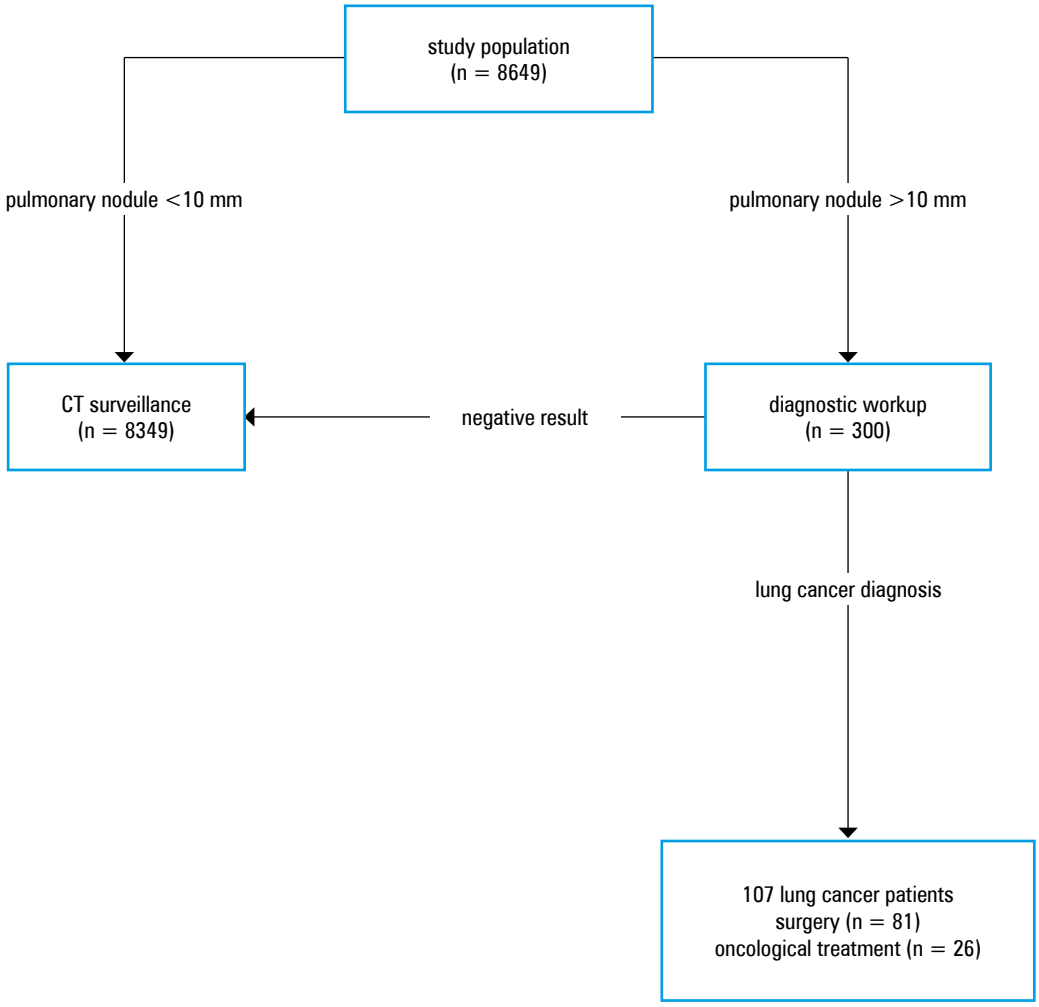

FIGURE 1 Study protocol
Abbreviations: CT, computed tomography

(39.2%) with a diameter of less than 10 mm (92%) (FIGURE 2).

Among the 2116 additional findings, mediastinal lymph node enlargement was the most common (755 cases, 35.6%).

A similar nodule size was recorded in 4512 follow-up CT examinations (84.6%), while an increase or decrease in size was observed in 619 examinations (11.6%) and 198 examinations (3.7%), respectively. In 581 of 10 290 consulted examinations (5.64%), the nodule estimation results were incongruent between consultants and radiologists.

A diagnostic workup was performed in 300 individuals. In 227 cases (75%), the workup was done after the first screening round. Transthoracic fine-needle aspiration biopsy was successful in 44 of 82 patients (61%) with lung cancer who were diagnosed by LDCT. In the remaining 37 cases, surgery was performed on the basis of radiological criteria of malignancy. Complications such as pneumothorax (42%) and lung hematoma (7%) occurred in 49 of 233 (21.0%) of diagnosed individuals, 17 of whom (7.3%) required chest-tube drainage. The number and type of diagnostic procedures are listed in TABLE 1.

A total of 180 patients (60.0%) were referred for further follow-up, and 125 patients underwent surgery. Five operations were performed without previous diagnostic workup owing to a difficult localization of the lesion. Lung cancer was diagnosed in 107 patients (1.24%), 78 of whom (72.9%) were diagnosed after the first round of screening. The majority of subjects with lung cancer (66.4%) had stage I or II cancer according to the 7th edition of the TNM classification. Eighty-one patients (75.7%) underwent surgery with a curative intent, and 26 patients received oncological treatment. There were no deaths in the surgical group, and the rate of complications was as low as 15%. Adenocarcinoma (including bronchoalveolar carcinoma) was the most common finding on histology (63.6%) followed by squamous cell carcinoma (22.4%). The majority of surgical patients underwent lobectomy (video-assisted, in 30 patients; open, in 38 patients). Three patients (2 in pathological stage IIIA and 1 in stage IIB) underwent pneumonectomy. The mean length of hospital stay was 8 days (range, 5–48 days). Stage I NSCLC was detected in 64 of the surgical patients (79.0%). There were 24 futile thoracotomies (54.5%) among 44 surgeries for nonmalignant lesions. Nine patients had tuberculomas; three, mediastinal tumor; and one, neurofibroma, in which surgery is recommended (TABLE 2). The most common findings in the benign group were tuberculoma (20.5%) and local fibrotic or atelectatic changes

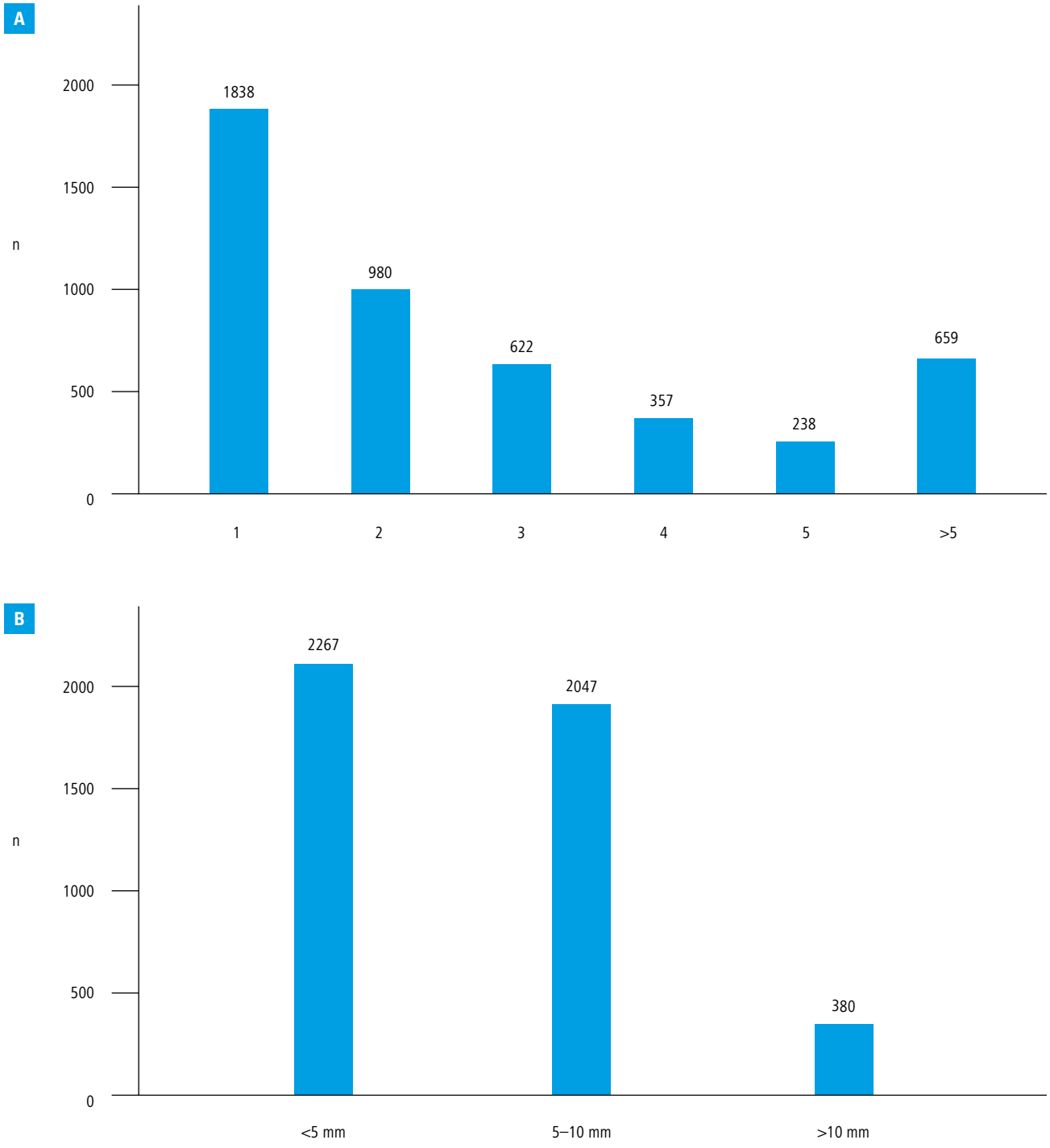

FIGURE 2 Number of detected nodules (**A**) and their diameter (**B**); a total of 4694 positive results (54%)

TABLE 1 Diagnostic workup: number and type of diagnostic procedures

	n	Lung cancer, n	%
fine-needle aspiration biopsy	233	50	21.5%
bronchoscopy	253	11	4.3%
EBUS	8	4	50%
mediastinoscopy	11	5	45.5%
scalene node biopsy	5	1	20%
videothoracoscopy	3	2	66.6%

Abbreviations: EBUS, endobronchial ultrasound-guided biopsy of mediastinal lymph nodes

(31.8%). There were no deaths in the nonmalignant group, and the complication rate was 11%. The characteristics of the surgical patients are shown in TABLES 2 and 3.

Most of the participants remain under observation outside the program. A total of 254 deaths (2.94%) were recorded until November 2013 in the study cohort: 129 (50.8%) were cancer-related, 67 (26.4%) were due to cardiovascular causes, and 60 (22.8%)—due to other reasons.

DISCUSSION The detection rates of 54% via LDCT screening in this study and of 32% of cases

TABLE 2 Characteristics of resected nonmalignant lesions

number of surgical patients	44
mean age, y	60.5
women, n	23
men, n	21
current smokers, n	26
former smokers, n	18
pack-years, range	7.5–100
mean pack-years	37.1
mean nodule size, mm	13.2
histology, n	
tuberculoma	9
hamartoma	7
sarcoidal tumor	1
focal fibrosis and atelectasis	14
mediastinal cyst	4
chest wall lipoma	2
neurofibroma	1
pleural lymph node	1
emphysema	2
atypical adenomatous hyperplasia	1
thymic adipous tissue	1

referred for secondary screening are higher than those reported previously (ranging from 1.6% to 53%).[11,12] This results from the fact that our protocol defined every found nodule as positive irrespective of a radiological analysis. By using our experience, we could substantially reduce the number of positive results that required further follow-up. This same factor will also reduce unnecessary diagnostic workup, which was higher in our study than in previous studies,[12-16] mainly because diagnostic procedures were performed in our study for nodules larger than 10 mm in diameter instead of 15 mm, as performed in some other studies.[13,17-22] The lung cancer detection rate of 1.24% in this study is in line with most published data[11,13,14,16,20,23] (TABLE 4).

The proportion of stage I and II cancers was much higher (66.4%) than that observed in general practice but lower than that reported by Henschke et al.,[4,15] whose cohort consisted primarily of individuals with stage I NSCLC (85%). A careful recruitment of each volunteer by health care employees is necessary to obtain such a result. One-fourth of the surgical patients underwent futile thoracotomies.[24] This number should definitely be reduced, although it does not differ substantially from that observed in our daily practice. During this same period, 20% of patients with nonmalignant lesions underwent surgery in our department, outside the screening program.

Lung cancer screening has evolved slowly since 1966 when Lilienfeld et al.[25] published their series of 14 607 volunteers who underwent chest X-ray and sputum examinations to detect the presence of lung cancer. Since 1992, LDCT has been proposed as a screening tool, and the results of several studies have been inconsistent.[1,6] The National Lung Screening Trial, which reported a reduction in mortality greater by 20% in the LDCT screening arm than in the chest X-ray arm, changed the landscape of lung cancer screening[5] by shifting the focus from "whether" screening should be performed to "how" screening should be performed and implemented. The era of studies focused on specific questions in the fields of radiological assessment, indications, organizational aspects, and other practical issues related to lung cancer screening using LDCT has arrived.

Our "open-access" observational study covered the region of Pomerania in northern Poland to simulate a potential application of LDCT screening. The study comprised 19 radiology centers that were evenly spread across the voivodeship, and thus, accessibility was similar for the entire population. The number of follow-up LDCTs was limited only to a 12-month period owing to time restrictions forced by the program. However, most of the volunteers are under observation outside the program. We practically educated a significant number of health care employees in the region about lung cancer diagnosis and treatment as well as LDCT screening principles. This, together with the experience of the radiologists involved in the program will provide an excellent network for further studies, and, in our opinion, the development of this network represents one of the most useful results of the program. We have tested the "centralized" pattern of screening design with 1 institution having a full control over the examinations, analysis of patient findings, and subsequent diagnosis and treatment (TABLE 5). When the family doctor is not directly involved in referring a smoker for such a screening, all responsibility concerning the explanation of positive computed tomography results must be provided by the team. In our opinion, the major drawbacks in our program design was the lack of psychologists and smoking cessation program in the outpatient setting.

Open-access protocols without the involvement of general practitioners have been used in other studies[13,17,26,27] and resulted in better recruitment than that observed in the studies involving general practitioners.[18-20,28,29] The interest of participants was enormous, as underlined by the more than 2000 registrations on the program website during the first 4 days of enrollment. For practical reasons and time constraints, we were forced to discontinue website recruitment. These findings indicate that problems with recruitment in previous breast and cervical cancer programs in Poland were not applicable to LDCT screening. However, this form of recruitment has important drawbacks. We observed that a substantial proportion of volunteers overstated their smoking histories to be accepted in the study. Two never-smoking women with a pulmonary nodule (1 tuberculoma and 1 NSCLC) underwent surgery. Internet blogs provided instructions on

TABLE 3 Characteristics of lung cancer patients (n = 107; 1.24%)

	No.	%
mean age, y	62.3	–
women	43	40.2
men	64	59.8
current smokers	77	72.0
former smokers	30	28.0
pack-years	5–120	–
mean pack-years	41.5	–
mean nodule size, mm	19.8	–
histology		
squamous cell carcinoma	24	22.4
adenocarcinoma	54	50.5
bronchoalveolar carcinoma	14	13.1
carcinoid	4	3.7
small cell carcinoma	11	10.3
mix-type (NSCLC + SCLC)	2	1.9
stage: all lung cancers		
Ia	54	50.5
Ib	11	10.3
IIa	2	1.9
IIb	4	3.7
IIIa	27	25.2
IIIb	3	2.8
IV	6	5.6
stage: resected lung cancer	81	
Ia	53	65.4
Ib	11	13.6
IIa	2	2.5
IIb	4	4.9
IIIa	10	12.3
IIIb	0	0.00
IV	1	1.2

Abbreviations: NSCLC, non-small cell lung cancer; SCLC, small cell lung cancer; VATS, video-assisted thoracic surgery

TABLE 4 Simulation of the detection rate with changed inclusion criteria

New inclusion criteria	Number of CT examinations	Number of detected LCs	Number of missed LCs	LC detection rate
age >55 y	7392	96	11	1.30%
smoking history >30 pack-years	5489	91	16	1.66%
age >55 y and smoking history >30 pack-years	4804	87	20	1.81%

Abbreviations: LC, lung cancer; others, see **FIGURE 1**

TABLE 5 Characteristics of different radiological centers

Radiological center	CT scans, n	%	Diagnostic workup, n	%	Lung cancer diagnosis, n	%
Medical University of Gdańsk	5505	63.65	217	72.33	76	71.03
other centers	3144	36.35	83	27.67	31	28.97

Abbreviations: LC, lung cancer; others, see **FIGURE 1**

how to effectively apply for the study. In total, 1020 volunteers (12%) reported a smoking history of exactly 20 pack-years, and, potentially, most of the "biased" participants are included in this group. Additionally, a higher proportion of stage III and IV lung cancers was detected in our study (33.6%) in comparison with other studies because some individuals hid symptoms that would have been discovered in a careful case history evaluation.

The detection rate of lung cancer in LDCT screening appears to be low considering the overall morbidity of patients with this malignancy. Conversely, when compared to cervix cancer or breast cancer screening, its effectiveness is at least as good. Nevertheless, it is obvious that other tests should be developed to better define the high-risk group for lung cancer. This appears to be the only means of enhancing the effectiveness of LDCT screening and its economical value, which will result in a broad application of this screening method.

Contribution statement WR conceived the idea for the study. WR, MJ-G, RD, JK, TZ, JS, and MS contributed to the design of the program. All authors were involved in data collection. WR, MJ-G, RD, and JK analyzed the data. JK, IB, MJ-G, and RD coordinated implementation of the project. All authors edited and approved the final version of the manuscript

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ARTYKUŁ ORYGINALNY

Wyniki otwartego programu badań przesiewowych raka płuca wykorzystującego niskodawkową tomografię komputerową – wyniki z Gdańska

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SŁOWA KLUCZOWE

rak płuca, tomografia komputerowa, wczesna diagnostyka raka

STRESZCZENIE

WPROWADZENIE Badanie przesiewowe raka płuca z wykorzystaniem niskodawkowej tomografii komputerowej (*low-dose computed tomography* – LDCT) stanowi jedno z najbardziej obiecujących narzędzi mogących obniżyć śmiertelność z powodu raka płuca.

CELE Celem badania była ocena wyników otwartego programu badań przesiewowych wykorzystującego LDCT.

PACJENCI I METODY 8649 bezobjawowych uczestników w wieku od 50 do 75 lat, z historią palenia tytoniu co najmniej 20 paczkolat, zostało poddanych badaniom przesiewowym przy zastosowaniu LDCT. Obecność guzków w płucu o średnicy do 5 mm wymagała badania kontrolnego po 12 miesiącach, natomiast tych o średnicy 5–10 mm – po 3, 6 i 12 miesiącach. Osoby z guzem przekraczającym 10 mm wymagały dalszej diagnostyki.

WYNIKI U 4694 (54%) osób wykryto zmianę o charakterze guzka płuca. Rak płuca został wykryty u 107 (1,24%) uczestników. Z 8649 uczestników programu do dalszej diagnostyki zakwalifikowano 300 (3,5%), a 125 (1,5%) zostało poddanych resekcji chirurgicznej (81 z powodu zmiany złośliwej, 44 – zmiany łagodnej). 81 osób zostało poddanych leczeniu chirurgicznemu z intencją radykalną, a 26 osób – leczeniu onkologicznemu. Nie stwierdzono okołooperacyjnych zgonów. U większości pacjentów chirurgicznych wykonano lobektomię (wideotorakoskopową u 30 pacjentów i otwartą u 38 pacjentów). Stadium I zaawansowania niedrobnokomórkowego raka płuca stwierdzono u 64 (79%) operowanych pacjentów.

WNIOSKI Odsetek wykrytych raków płuca w badaniu przesiewowym z zastosowaniem niskodawkowej tomografii komputerowej jest stosunkowo niski, ale pacjenci są diagnozowani we wczesnym stadium zaawansowania w porównaniu z codzienną praktyką kliniczną.

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