

The R.I.S.P. oncology screening project, an experience at the IRCCS INT PASCALE in Naples: comparison between LDCT protocols using 64-slice and Dual-source 128-slice equipment.

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ABSTRACT

The RISP (Italian Network for Lung Screening) project is a research program funded by the Ministry of Health. Several cancer centers in Italy, including the IRCCS Fondazione “G. Pascale” in Naples, have participated in the project, aiming to achieve early diagnosis of lung cancer. As part of the larger 4-iTLR (Four in the Lung Run) project [1], which involved a total of 25,000 patients, including 10,000 Italians, our IRCCS contributed 864 patients. The project recruits volunteers based on predefined inclusion criteria, who undergo low-dose multidetector computed tomography (LDCT) of the lung volume. The collaboration and interaction of professionals such as radiology technicians, radiologists, thoracic surgeons, and data managers places patients on a free, highly skilled path. Based on the radiological findings, patients with benign lung nodules were randomized into two groups: group A with follow-up low-dose CT scans one year after the initial examination and group B with follow-up low-dose CT scans two years after the initial examination. All individuals with a positive LDCT underwent further investigations for a potential lung cancer diagnosis. The RISP project will contribute to reducing mortality from lung cancer and potentially from other smoking-related diseases by developing an early diagnosis system that uses chest LDCT at variable intervals, based on each patient’s individual risk.

INTRODUCTION

The RISP (Italian Network for Pulmonary Screening) project (Figure 1) is a research initiative supported by the Ministry of Health. It involves 18 oncology centers in 15 different regions across the country, including the IRCCS Fondazione “G. Pascale” in Naples (Figure 2). Its aim is to achieve early diagnosis of lung cancer. In Italy, approximately 42,000 new lung cancer diagnoses are recorded each year, and in approximately 80% of cases, the disease is detected in an advanced stage [2]. Identifying the tumor at an early stage is therefore essential to ensure faster and more effective therapeutic interventions. The project is based on a multidisciplinary approach involving various professionals, including radiology technicians, radiologists, thoracic surgeons, and data managers. This collaboration allows patients to be included in a free screening program, characterized by high standards of quality and expertise [13]. The objective of the R.I.S.P. project is (Italian Pulmonary Screening Network) (Figure 3) is to diagnose lung cancer early in high-risk subjects, through the use of low-dose CT (LDCT) and to offer support for smoking cessation, also through the prescription of natural drugs including cytisine. This also allows for

the validation of the use of CT protocols that minimize radiation exposure to the patient [3,6,7,8]. In the long term, screening aims to collect data to be fully integrated into the National Health Service and integrated into the LEA, as is the case for other tumors, reducing mortality.



Figure 1



Figure 2



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MATERIALS AND METHODS

Starting from a larger project, the 4-iTLR (Four in the Lung Run), which recruited 25,000 patients, including 10,000 Italians, 864 patients were enrolled in our IRCCS. Inclusion criteria for the project were: age 55 to 75, heavy or ex-heavy smoker (stopped less than 15 years ago), smoker with an average consumption of 20 cigarettes per day for 30 years or 40 cigarettes per day for 15 years, cancer-free for at least 5 years, and signed informed consent for study enrollment and data processing. Exclusion criteria were: severe chronic disease (severe respiratory and/or renal and/or hepatic and/or cardiac failure), serious psychiatric problems, and alcohol or other substance abuse [2]. In the initial screening period, starting from November 2022, the Radiodiagnosics Unit (U.O.C.) performed a low-dose, multidetector 64-slice CT scan according to SIRM (Italian Society of Medical Radiology) guidelines. The acquisition parameters were: volumetric acquisition without contrast medium, inspiratory apnea, Z-axis extension of the lung apices and costophrenic sinuses, crano-caudal or caudocranial acquisition direction, 120 kVp and 20-40 mAs as per the screening protocol, slice thickness ≤ 1.5 mm, rotation time 200-500 ms, and a high spatial frequency reconstruction algorithm. A new 128-slice Dual Source CT scanner was installed starting from January 2025. The acquisition parameters were: volumetric acquisition without contrast medium, inspiratory apnea, extension on the Z-axis of the lung apices - costophrenic

sinuses, acquisition direction crano-caudal or caudo-cranial, kVp and mAs set using CAREdose 4D and CareDose KV with automatic modulation (120 kVp and approximately 20-40 mAs), to limit the dose absorbed by the patient, rotation time 280-300 ms, fine collimation at ≤ 1.5 with excellent yield of retroreconstructions ≤ 1 [5]. In both volumetric acquisitions with the respective equipment, the effective dose was 1-3 mSv, falling within the spectrum of effective doses required by screening (Table 1). The images were read using an automated CAD (Computer-Aided Detection/Diagnosis) system and centralized supervision with a second reading by an expert radiologist (> 10 years of lung screening), with the images and a standardized CT scan evaluation form sent to the recruitment center (IRCCS Istituto Nazionale Tumori di Milano) in compliance with current legislative requirements within 10 days [4]. The management of the identified pulmonary findings was carried out following a diagnostic algorithm that allows standardizing the management of the identified nodules and reducing unnecessary diagnostic checks and investigations (Lung-RADS - Update 1.1, 2019 - American College of Radiology) [1]. To optimize the communication of the results between colleagues from other disciplines, the standardized form was used which included: characteristics of any suspicious lesions, presence of significant collateral findings, conclusions and follow-up recommendations with the Lung-RADS category of the lesions.



TC ad Alta Risoluzione (HRCT)	Principali indicazioni: studio della patologia parenchimale polmonare (incluso il nodulo polmonare)	
Preparazione	Non indicata	
Posizione del paziente	Supina	Prona L'acquisizione a Paziente prono è indicata nei casi in cui sia necessario distinguere alterazioni interstiziali periferiche da opacità gravitazionali
Fase Respiratoria	Inspiro	Acquisizione in espriro È necessaria per identificare l'intrappolamento aereo. È indicata quando viene identificato il pattern a mosaico nella scansione inspiratoria e/o in caso di patologia ostruttiva/sospetta tracheomalacia
Acquisizione	Volumetrica senza mdc	La tecnica sequenziale assiale (e.g., intervalli di 10-20 mm) può essere utilizzata nel paziente pediatrico e per la scansione espiratoria
Estensione su asse Z	Apici polmonari - seni costofrenici	
Scan direzione	Crano-caudale o caudo-craniale	
Parametri di acquisizione	HRCT Standard	HRCT Low-Dose
kVp	120	120
mAs	Modulazione automatica (si suggerisce l'utilizzo del fuoco fine ove possibile)	20-40 (es. screening)
Spessore di strato	$\leq 1,5$ mm	$\leq 1,5$ mm
Rotation time	200-500 ms	200-500 ms
Algoritmo di ricostruzione	Alta frequenza spaziale	

Figure 3.

RESULTS

To date, 864 baseline LDCT scans have been performed (Table 2). Patients with benign-appearing pulmonary nodules (Figure 4) were randomized into two groups (Table 3): Group A, consisting of 332 patients, underwent a low-dose CT (LDCT) follow-up one year after the initial examination, and Group B, consisting of 532 patients, re-evaluated with LDCT two years after the initial examination. Patients with an indeterminate outcome (Figure 5) continued screening at the scheduled interval according to the Lung-RADS guidelines. Based on current imaging data, follow-up CT scans for 544 patients occurred at 3 months for 23 patients, 6 months for 108, 12 months for 39 volunteers, and 24 months for 374 subjects. Ten patients underwent surgery, and five were diagnosed with lung cancer (Figure 6). Currently, two-year follow-up is underway on 85 patients in arm B to conclude the project. Regarding cytisine use, 176 patients voluntarily took the drug, and 23 did not accept the drug therapy. Finally, 131 volunteers quit smoking, while 22 patients continued to smoke.

DISCUSSION

The CTDIvol mGy and DLP mGycm values used in analyzing a sample of 10 patients undergoing follow-up CT scans on 64-slice CT and 128-slice dual-source CT between 2023 and 2026 demonstrated an average dose distribution that was similar or slightly lower than that of dual-source 128-slice CT (Table 4). Dual-source CT allowed for the acquisition of high-definition, high-diagnostic quality images, essential for studying the fine structures of the lung parenchyma, identifying very small nodules and vessels and early lesions. The rapid acquisition of the exam reduced patient discomfort, especially for claustrophobic patients or those with breathing difficulties (Table 5). At the same dose, 64-slice CT provided lower-quality images, particularly for obese patients. Furthermore, it was found that the presence of massive coronary calcifications can cause “bloom” artifacts, meaning that they appeared enlarged compared to their real proportions and made the evaluation of the residual vascular lumen complex. Image reconstruction was based on iterative algorithms [12,13]. The 64-slice CT used the ASiR (Adaptive

TABLE 2.

TC BASELINE	864
ESAMI TOTALI	544
TC 3 months	23
TC 6 months	108
TC 12 months	39
TC 24 months	374
PET	80

TABLE 3.

ARM A (ANNUAL) 332	332
ARM B (BIENNIAL) 532	532



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Figure 4: 5.17 mm nodule, midlobe (BENIGNE NODULE – RANDOMIZATION 1-2 YEARS).

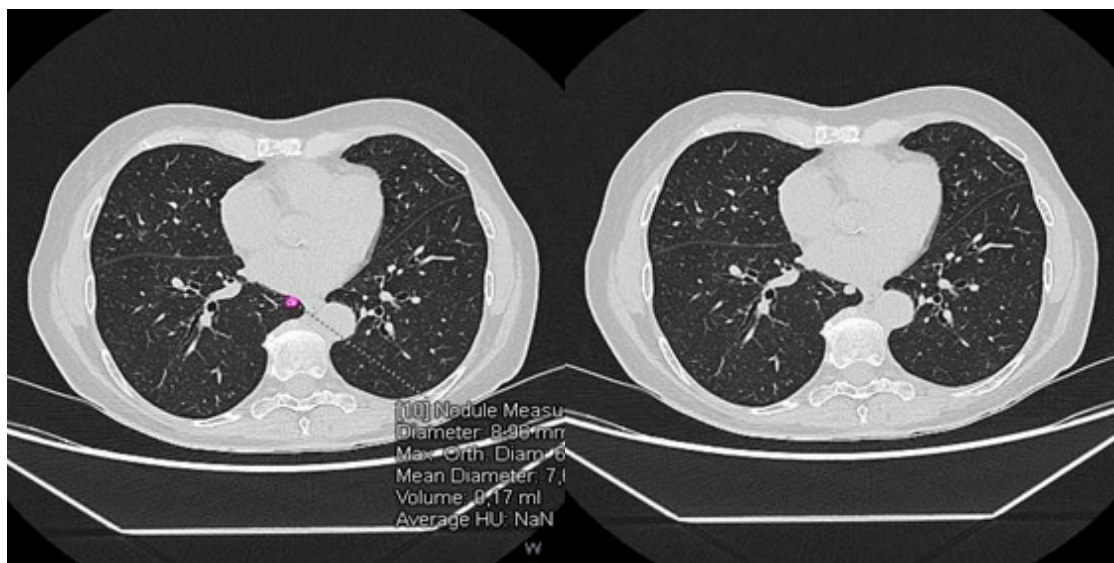


Figure 5 Nodule measuring 7.65mm in mean diameter, right lower lobe (INDETERMINATE NODULE – FOLLOW UP AT 6 MONTHS).

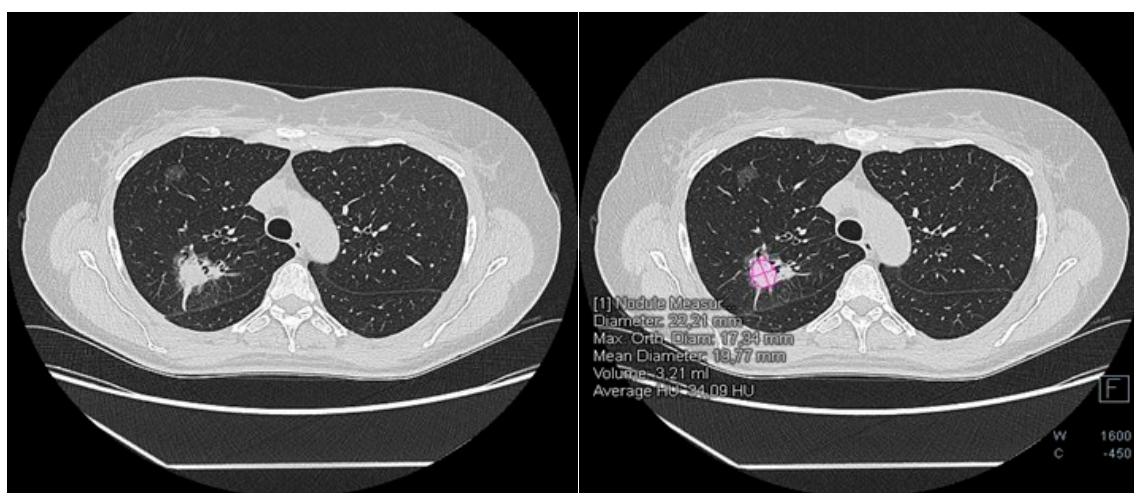


Figure 6 Heteroplastic lesion of 19.77mm, right upper lobe (MALIGNANT NODULE – FURTHER INVESTIGATIONS).

Statistical Iterative Reconstruction) system, which was the first significant step towards dose reduction (up to 40-50% less) while maintaining good image quality. ASiR modeled the statistical noise in the raw data and reduced it through subsequent iterations. The 128-slice CT used the SAFIRE (Sinogram Affirmed Iterative Reconstruction) system. This was based on raw data and allowed a dose reduction of up to 60% compared to traditional filtered back projection (FBP). SAFIRE acted on two levels: in the raw data space (sinogram) to reduce noise and in the image domain to correct artifacts, improving image sharpness [9,10,11].

The system that supported the radiologist in identifying and characterizing pulmonary nodules was CAD (Computer-Aided Detection/Diagnosis). IRC-CS Pascale adopted the Syngo Lung CAD system for lung screening. This software, based on artificial intelligence and deep learning algorithms, automatically analyzed CT images and flagged possible nodules or lesions, reducing the risk of false negatives. The system examined the lung parenchyma, identified solid, subsolid, or ground-glass nodules, and flagged suspicious areas to the radiologist. It provided volumetric and diameter measurements of the nodules and monitored their growth over time in



TABLE 4.

	TC 64		TC 128 Doual Source	
Patient sample	CTDIvol (mGry)	DLP (mGycm)	CTDI vol (mGry)	
Patient 1	3.46	152.82	4.43	
Patient 2	3.43	118.02	3.04	
Patient 3	2.59	109.32	3.92	
Patient 4	2.58	94.50	2.24	
Patient 5	3.44	125.66	4.11	
Patient 6	3.45	141.81	2.98	144.2
Patient 7	2.58	91.26	2.64	104.5
Patient 8	3.02	116.28	1.53	54.6
Patient 9	3.45	140.64	2.72	108.8
Patient 10	3.89	143.98	2.41	80.3

TABLE 5.

	TC 64	TC 128 Doual Source
CHEST CT ~ 5-7 mSv		
Dose nello screening	~1-1,5 mSv	~0.8-1.2 mSv (similar or slightly lower)
Tempo di acquisizione	+	++
Risoluzione spaziale e di contrasto	+	+++
Copertura per rotazione	+	+++



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follow-up CT scans. It allowed the characterization of the lesions to be assessed, considering density, margins, shape, and relationship to the bronchi. The advantages of CAD included: reduced image viewing and reporting times, increased diagnostic sensitivity, and standardized measurements. Limitations encountered were in some cases false positives (vessels, scars, artifacts), variable performance in case of very small nodules (<3 mm), diffuse opacities and complex pathological parenchyma.

CONCLUSIONS

The RISP project aims to reduce lung cancer-related mortality and, indirectly, mortality associated with other smoking-related diseases through the development of an early diagnosis model based on the use of thoracic LDCT at differentiated intervals ba-

sed on individual risk profiles. Specifically, the use of 128-slice dual-source CT at the same dose as 64-slice CT provides images with superior spatial and contrast resolution, faster acquisition speed, and improved temporal resolution, identifying micronodules <3 mm and distinguishing small opacities in the lung parenchyma (Figure 1). The use of artificial intelligence through CAD does not replace the radiologist in image viewing and reporting, but it significantly reduces exam evaluation times. The results of the randomized clinical trial conducted on both devices will allow, despite minor technical differences, the validation of a personalized screening protocol based on individual risk, with a favorable impact on the long-term economic sustainability of screening.

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