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Lung cancer screening with low-dose CT integrated with pulmonary care in a public hospital in southern Brazil: results from the first 712 patients

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ABSTRACT

Objective: To describe the performance of a pulmonologist-led lung cancer screening program using low dose CT (LDCT) in a cohort of outpatients with stable respiratory diseases in the Brazilian public health care system. **Methods:** This was a retrospective analysis of the first two rounds of lung cancer screening of patients enrolled in the program. Inclusion criteria were being between 55 and 80 years of age, being a current or former smoker (smoking cessation ≤ 15 years), and having a smoking history ≥ 30 pack-years. LDCT results were interpreted in accordance with the Lung CT Screening Reporting and Data System, and those with a score of 3 or 4 were considered positive screening. Incidental pleuropulmonary findings were sought in all reports. **Results:** LDCTs were requested for 791 patients during the study period, and 712 patients (90%) met the screening criteria. The mean patient age was 63 years, and most participants were current smokers (56%) with emphysema (78.5%) and other pleuropulmonary findings on CT (64%). Screening was positive in 14.0% and 5.6% of the cases in the first and second screening rounds, respectively. Lung cancer was detected in 1.5% of the patients in both first and second rounds (positive predictive value: 11.0% and 26.6%, respectively). The rate of early-stage (TNM I or II) screen-detected non-small cell carcinoma was 64.3%. Of the patients with positive screening, 19% were lost to follow-up before investigation was complete. **Conclusions:** The results of this screening program suggest its adequate performance in a cohort of patients with significant respiratory morbidity. The loss to follow-up rate highlights the need for constant monitoring and interventions to ensure adherence.

Keywords: Lung neoplasms; Diagnostic screening programs; Early detection of cancer; Brazil; Tuberculosis.

INTRODUCTION

Lung cancer causes more deaths than any other neoplasms worldwide, and a substantial and growing proportion of cases occur in regions of middle and low socioeconomic development.[1] In Brazil, advanced-stage lung cancer is identified in about 70% of diagnosed cases,[2] and the estimated number of deaths is 28,000 every year.[3] Low-dose CT (LDCT) screening in high-risk patients, followed by an appropriate diagnostic and therapeutic approach, reduces mortality from this disease by 20% or more, as demonstrated by large clinical trials in the United States and in Europe.[4,5] However, factors associated with the clinical-epidemiological profile of the screened population, as well as the local health care system, can potentially alter the benefits of screening.[6] Current international guidelines recommend continuing to study this strategy in different scenarios, as well as collecting data with a view to improving local programs.[6,7]

This study describes the results of a screening program developed for patients at high risk of lung cancer who were being followed up for lung diseases in a large public hospital in southern Brazil. Because the hospital is located in an area with a high incidence of granulomatous diseases, especially tuberculosis (89.9/100,000 population in the city of Porto Alegre and 46.6/100,000 population in the State of Rio Grande do Sul)[8] but also paracoccidioidomycosis[9] and silicosis,[10] there is specific interest in the potential large number of positive screenings associated with inflammatory nodules. In addition, little is known about the feasibility of a lung cancer screening program in the Brazilian public health care system.

METHODS

This was a retrospective analysis of all patients who underwent LDCT at the institution between the implementation of the lung cancer screening program

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(June of 2014) and December of 2019. The centralized registry of all LDCTs allowed the location of all patient records for review. In the program's care routine, pulmonologists requested LDCTs during outpatient visits of patients with lung diseases and smokers who were already being followed at the hospital. Data on demographics and clinical history, in addition to spirometry test results and imaging controls, were available in the electronic medical records and were collected using a structured form. Clinical data from the examination request and previous consultations were reviewed to confirm the intent to screen. The main follow-up diagnosis was recorded as reported by the pulmonologist in the medical records. COPD was confirmed by spirometry, but patients with evidence of chronic bronchitis were also considered COPD cases. Data were recorded anonymously and the project's ethical and methodological aspects were approved by the institution's research ethics committee (CAAE 73309317.5.0000.5530). Partial results of the present study have been previously presented as a poster at a conference.[11]

LDCT protocol

The acquisition and processing of images followed the American College of Radiology recommendations.[12] In summary, LDCT was performed with a 16-channel scanner (BrightSpeed; GE Healthcare, Waukesha, WI, USA) without the use of intravenous contrast, according to the following parameters: 120 kVp; 60 mA; gantry rotation time, 0.5 s; and pitch, 1.375. A single acquisition was performed during inspiration, and subsequent reconstructions were performed with 20-mm collimation, 5-mm increment, and 1.25-mm thickness. Effective radiation doses ranged between 0.8 and 1.3 mSv, with a dose-length product between 69 and 86 mGy•cm. The results were interpreted in accordance with the Lung CT Screening Reporting and Data System (Lung-RADS) standards,[13] and the revised assessment categories (version 1.1; 2019) were used whenever relevant. The reports were completed by radiologists from the institution under the supervision of a certified radiologist, who had developed the program and had specific training in thoracic radiology. The reports included the Lung-RADS classification score, as well as information on the presence of emphysema and other incidental pleuropulmonary findings. These findings included all acute or chronic interstitial, parenchymal, and pleural abnormalities that were described in the report but not used for the Lung-RADS classification.[13] Findings about other thoracic and extrathoracic organs, although described in the report, were not recorded in the present study.

Inclusion criteria were being between 55 and 80 years of age; having a smoking history of at least 30 pack-years; and being a current smoker or a former smoker (cessation ≤ 15 years). Exclusion criteria were having a pulmonary or systemic disease that would limit the diagnostic investigation or a possible surgical treatment for lung cancer (defined by the attending physician at the time of requesting the exam); having symptoms or signs compatible with clinical suspicion of lung cancer at the time of LDCT request; and having had lung cancer previously.

The procedures for investigation after positive screening (including control CT, biopsy, or referral for surgery) were at the discretion of the attending pulmonologist, although suggestions on the LDCT report in accordance with the Lung-RADS standards[13] were also considered. As part of the program's routine, most control CTs were also LDCTs, and their reports also followed the Lung-RADS standards.[13] Regular multidisciplinary sessions were not a formal part of the screening program, and difficult cases were individually discussed between the radiologist, the thoracic surgeon, or both, as the routine practice at the institution.

The analysis of the present study refers to the outcomes in the first (T0) and second (T1) rounds of screening. Clinical and radiological outcomes were evaluated for every patient after a positive screening, including control CT results and final results of additional diagnostic workup (cancer or benign disease). The Lung-RADS standards[13] were used in order to determine the stability or regression of the lesion in control CTs. The medical records of patients with positive screening were reviewed until diagnostic definition or follow-up loss/closure. Additional data from patients diagnosed with cancer by screening were collected, including histological type and details on staging and treatment.

The parameters adopted to evaluate the program's performance were defined as follows: rate of positive screens—number of patients with a Lung-RADS score of 3 or 4 divided by the number of patients screened, the rate being calculated for T0 and T1 separately; prevalence of lung cancer—number of patients with confirmed lung cancer in T0 divided by the number of screened patients in T0; incidence of lung cancer—number of patients with confirmed lung cancer in T1 divided by the number of screened patients in T1; and positive predictive value—number of patients with confirmed lung cancer divided by the number of patients with positive screening.

As an additional element of investigation, non-small cell carcinoma cases detected by screening were compared with cases diagnosed outside the program at the same institution (patients whose investigation was initiated due to symptoms or incidental findings). This comparative sample consisted of all cases diagnosed outside the screening program in 2017, which was the midpoint of the study period.

Statistical analysis

Descriptive statistics (absolute and relative frequencies; means and standard deviations; and medians and interquartile ranges) were used for reporting data on the prevalence of positive screenings and neoplasms, as well as clinical-epidemiological variables. The chi-square test was used for comparison

of frequencies of positive screening between patients with and without additional CT findings, as well as for comparison of early-stage lung cancer between screened and unscreened patients (comparative sample). The significance level was set at 0.05 for all results.

RESULTS

During the study period, LDCT was performed in 791 patients. In 79 of these patients (10%), LDCT was not requested for screening purposes or the patient did not meet the inclusion criteria of the program. The reasons for excluding these patients are detailed in Figure 1. Of the 712 patients who underwent the first round of screening (T0), 266 (37.3%) underwent the second round (T1) by the end of the study period. Clinical and demographic data of the patients are shown in Table 1. Briefly, the mean age was 63 years, and there was a slight predominance of men (51.5%) and current smokers (56%). The most common diagnosis was COPD, which was the main diagnosis in 69.3% of the patients. The mean FEV_1 was 64.9% of the predicted value.

The rate of positive screenings in T0 was 14%, with a similar distribution between Lung-RADS scores of 3 and 4 (Table 2). In T1, among 266 patients, 15 (5.6%) of the screenings were positive. Overall, 16 cases of cancer were identified in the study: 15 were cases of primary lung cancer and 1 was a case of metastatic breast cancer (the primary tumor had not been diagnosed prior to screening). Of the 15 primary lung malignancies, 11 were identified in T0 (n = 721; cancer prevalence of 1.5%), as were 4 in T1 (n = 266; cancer incidence of 1.5%). The positive predictive value for positive screening in T0 was 11% (11 confirmed neoplasm cases/99 positive screenings). Considering only a Lung-RADS score of 4, the positive predictive value was 23.9% (11/46). In T1, the positive predictive value was 26.6% (4/15) for positive screening and 50% (4/8) for Lung-RADS 4.

Details on the patients diagnosed with lung cancer, including staging and treatment, are shown in Table 3. The most common histological type was adenocarcinoma (13/15 patients), and treatment with curative intent (surgery or ablative radiotherapy) was offered to all stage I or II patients. A comparison of staging of non-small cell carcinoma detected in the screening program with those detected outside the screening program in 2017 (n = 134) is shown in Figure 2. TNM staging I-II was found in 64.3% and 22.4% of screened and unscreened patients, respectively (percentage point difference = 41.9%; 95% CI: 15.2-62.2; p = 0.0007).

Table 4 shows the outcome of the 114 positive screenings (T0 and T1), including the proportion of cases in which the Lung-RADS score regressed on subsequent CTs. One important finding was that 19.3% (n = 22/114, T0 and T1 combined) of the patients with positive screening were lost to follow-up without completing the investigation: 18.3% with a Lung-RADS score of 3 and 20.3% with a Lung-RADS of 4 (T0 and T1 combined).

Incidental pleuropulmonary findings (in addition to emphysema) were described in 64% of the CT scans, including parenchymal bands/cicatricial atelectasis in 37.9% of the cases. The frequencies of positive screening between patients with and without incidental LDCT findings were similar (16.4% and 12.5%, respectively; percentage point difference = 3.9; 95% CI: −1.3 to 9.6; p = 0.15). There was no statistically significant difference between patients with and without emphysema on LDCTs (15% and 9.8%, respectively;

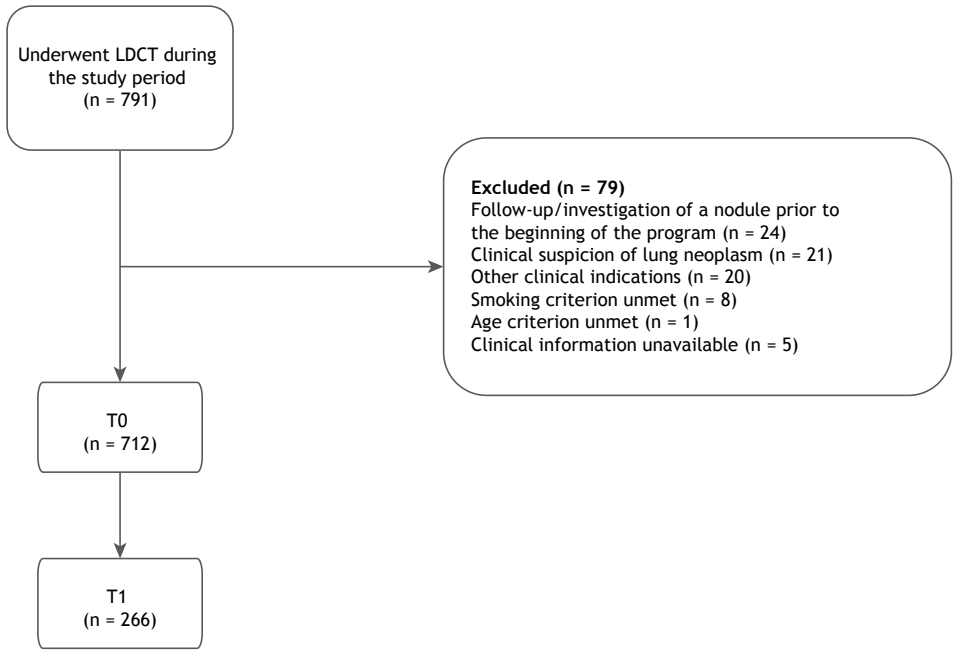

Figure 1. Flow chart of the participant selection process. LDCT: low-dose CT; T0: first round of screening; and T1: second round of screening.

Table 1. Characteristics of screened patients (N = 712).[a]

Characteristic	Result
Age bracket, years	
55-59	188 (26.4)
60-64	219 (30.7)
65-69	169 (23.7)
70-74	101 (14.2)
75-80	35 (4.9)
Age, years	63.0 ± 5.7
Sex	
Female	346 (48.5)
Male	366 (51.5)
BMI, kg/m^2	27.9 ± 5.4
< 30	438 (61.5)
≥ 30	198 (27.8)
Missing	76 (10.6)
Smoking	
Current	398 (56)
Former	296 (41)
Missing data	18 (2)
FEV_1, L	1.67 ± 0.69
FEV_1, % predicted	
≥ 80	188 (26.4)
50-79	274 (38.4)
30-49	164 (23)
< 30	33 (4.6)
Missing data	53 (7.4)
Main diagnosis[b]	
COPD[c]	494 (69.3)
Smoking cessation/counseling[d]	72 (10.1)
Tuberculosis sequelae	28 (3.9)
Asthma + COPD	26 (3.6)
Dyspnea assessment	24 (3.3)
Asthma	19 (2.7)
Previous pulmonary nodule[e]	8 (1.1)
Screening only	8 (1.1)
Interstitial disease	7 (0.9)
Bronchiectasis	5 (0.7)
Sleep apnea	4 (0.5)
Chronic cough	4 (0.5)
Preoperative screening	3 (0.4)
Chest pain	3 (0.4)
Silicosis	2 (0.3)
Sarcoidosis	1 (0.1)
Active tuberculosis	1 (0.1)
Paracoccidioidomycosis	1 (0.1)
Thrombophilia	1 (0.1)
Unreported/unavailable data	26 (3.6)

[a]Values expressed as n (%) or mean SD. [b]More than one diagnosis present in 25 patients. [c]Includes clinical diagnosis of chronic bronchitis, as well as cases associated with another diagnosis, except for asthma, which was described as ACOS. [d]Treatment/counseling as the main reason for outpatient follow-up. [e]Patients whose nodules had been identified and diagnosed as benign right before the beginning of the screening program were included in the study..

Table 2. Results obtained after the first round of low-dose CT (N = 712).[a]

Finding	Result
Negative screening	613 (86)
Lung-RADS 1	342 (48)
Lung-RADS 2	271 (38)
Positive screening	99 (14)
Lung-RADS 3	53 (7.4)
Lung-RADS 4	46 (6.5)
4A	26 (3.6)
4B	14 (2)
4X	6 (0.8)
Emphysema detected on LDCT	559 (78.5)
Incidental pleuropulmonary findings on LDCT[b]	
Any[c]	456 (64.0)
Parenchymal bands/cicatricial atelectasis	270 (37.9)
Compatible with respiratory bronchiolitis	118 (16.6)
Inflammatory opacities, other	70 (9.8)
Bronchiectasis	51 (7.2)
Interstitial abnormalities	33 (4.6)
Pleural thickening/calcification	10 (1.4)
None	256 (36.0)

Lung-RADS: Lung CT Screening Reporting and Data System score; and LDCT: low-dose CT. [a]Values expressed as n (%). [b]Except emphysema and pulmonary nodules included in Lung-RADS description. [c]More than one finding may occur in each patient.

percentage point difference = 5.2%; 95%CI: −1.15 to 10.1; p = 0.09).

DISCUSSION

Our study reports the initial results of a lung cancer screening program in a cohort of patients with specific characteristics that differ from others: it was developed in a setting of high prevalence of granulomatous diseases and conducted by pulmonologists for patients being already followed up for chronic stable respiratory diseases in the context of the Brazilian public health care system.

Although our inclusion criteria were practically the same as were those in the National Lung Screening Trial (NLST),[4] the patients included in our study had a different clinical profile, as expected in a cohort of patients with previous lung diseases in a different epidemiological context. In fact, in our study, emphysema was reported in 78.5% of the patients during the first round of LDCTs, which was much higher than that reported in the NLST (30.7%).[14] Similarly, only 10.6% had a history of COPD/emphysema in that study,[14] whereas, in our study, the main reason for respiratory follow-up was COPD (69.3%). Parenchymal bands/cicatricial atelectasis were also very frequent in our cohort, probably reflecting previous infections, including locally prevalent granulomatous diseases.

Despite these differences, the positive screening rates were quite similar according to the Lung-RADS classification: The proportion of Lung-RADS 3 or 4 was 13.6% and 14%, respectively, in the NLST reanalysis[15] and in our study. The same occurred with the prevalence of cancer: 1% and 1.5%, respectively.

In a context similar to that in this study, Grover et al.[16] evaluated a screening program in a population previously followed up for COPD in the United Kingdom public health care system. The prevalence of cancer was 2% and, more importantly, 66.7% of these cases were diagnosed at stage I or II. In our study, the proportion of early cases was similar (64.3%), and, of note, that was significantly higher than was the

Table 3. Description of 15 cases of primary lung cancer confirmed after positive screening.

Sex, Age (years)	Lung-RADS	Histology	TNM	Staging	Treatment
Positive screening (first round)					
Female, 59	4X	Adenocarcinoma	cT3 cN3 M1c	IVB	Chemotherapy
Female, 72	4A	Adenocarcinoma	pT1pN0M0	IA	Surgery
Female, 64	4A	Adenocarcinoma	pT1cN0M0	IA3	Surgery
Male, 63	4X	Adenocarcinoma	cT1b cN0 M0	IA2	Radiotherapy, curative intent (VMAT)
Female, 58[a]	4A	Adenocarcinoma	T1aN2M1c	IVB	Palliative radiotherapy
Female, 78	4B	Adenocarcinoma	cT1b cN0 M0	IA2	Surgery
Female, 61	4X	Small cell carcinoma	-	Extensive disease	? (oncology evaluation outside the screening center)
Female, 74	4B	Poorly differentiated carcinoma (probable squamous cell carcinoma)	cT3 CN3 M1b	IVA	Chemotherapy + targeted therapy (research protocol)
Female, 63	4B	Adenocarcinoma	pT3pN0M0	IIB	Surgery
Male, 77	4B	Adenocarcinoma	cT2aN0M0	IB	Initially refused treatment. Subsequent treatment outside the center.
Female, 55	4B	Adenocarcinoma	pT2aN0M0	IB	Surgery
Positive screening (second round)					
Male, 71	4B	Adenocarcinoma	pT1b pN0 M0	IA2	Surgery
Female, 55[b]	4X	Adenocarcinoma	T3N3M1a	IVA	? (oncology evaluation outside the screening center)
Male, 60	4A	Adenocarcinoma	pT2apN0M0	IB	Surgery
Female, 56	4B	Adenocarcinoma	T2 cN2 M1c	IV	Chemotherapy

Lung-RADS: Lung CT Screening Reporting and Data System score; and VMAT: volumetric modulated arc therapy. [a]Diagnosis/staging delayed for 13 months. [b]Delay between control CT and further investigation (suggestion, 6 months; completion, 22 months). Note: One case of breast cancer metastasis was not included in this analysis.

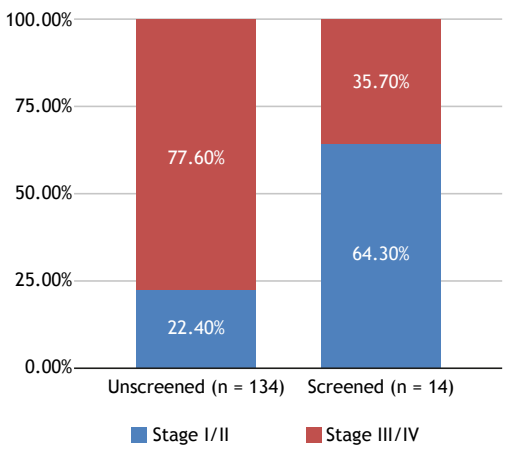

Figure 2. Staging of non-small cell lung carcinoma in patients participating in the screening program during the study period (2014-2019) and those not participating in the program in 2017 (midpoint of the study period).

proportion of cases detected outside the screening program in our institution (22.4%) and nationwide.[2] In fact, our results might have underestimated the potential benefit of screening, because a careful review of data revealed that in 2 of the stage IV cases, there was an unintentional delay in performing a control CT and diagnostic workup. Indeed, we cannot be sure whether avoiding these delays would have resulted in more favorable staging, and we understand that these situations may reflect real-life difficulties of a screening program.

One important concern is that patients with lung diseases and impaired lung function may present with a limited potential to treatment with curative intent. In our study, with the exception of 1 patient who refused treatment, all patients at TNM I or II received treatment with curative intent (surgery or ablative radiotherapy). Despite the significant number of patients with impaired lung function, including more than a quarter of the participants with FEV_1 < 50% of the predicted value, we believe that patients carefully selected on the basis of their overall clinical context may be suitable candidates for screening even at such levels of lung function impairment.

Screening with LDCT in developing countries is challenging, and efforts to study and implement it are still incipient.[17,18] Nevertheless, studies such as that by dos Santos et al.[19] demonstrate that cancer detection rates and the need for invasive investigation may be similar to those in developed countries. In fact, in a recent study by Hochhegger et al.,[20] who retrospectively evaluated the screening results of 3,470 patients in Brazil (88% from the private health care system), the results were quite encouraging: the prevalence of cancer was 2.1% and, more importantly, early staging was identified in 70.3% of these cases.

Table 4. Final clinical and/or radiographic outcomes after a positive screen (T0 and T1).[a]

Outcome after Lung-RADS 3	T0 (n = 53)	T1 (n = 7)	Total (n = 60)
Regression on early CT (up to 6 months)	28 (53.8)	3 (42.8)	31 (51.7)
Regression on CT (1 year)	8 (15.0)	1 (14.2)	9 (15.0)
Diagnosis of neoplasm	1[b] (1.9)	0 (0.0)	1 (1.7)
Diagnosis of benign disease	1 (1.9)	1 (14.2)	2 (3.3)
Loss to follow-up	9 (17.0)	2 (28.5)	11 (18.3)
Refused subsequent workup	0 (0.0)	0 (0.0)	0 (0.0)
Expectant treatment	6 (11.3)	0 (0.0)	6 (10.0)
Outcome after Lung-RADS 4	**T0 (n = 46)**	**T1 (n = 8)**	**Total (n = 54)**
Regression on early CT (up to 6 months)	12 (26.0)	3 (37.5)	15 (27.8)
Regression on CT (1 year)	3 (6.5)	0 (0.0)	3 (5.5)
Diagnosis of neoplasm	12[c] (26.0)	3 (37.5)	15 (27.8)
Diagnosis of benign disease	6 (13.0)	0 (0.0)	6 (11.1)
Loss to follow-up	10 (21.7)	1 (12.5)	11 (20.3)
Refused subsequent workup	2 (4.3)	1 (12.5)	3 (5.5)
Expectant treatment	1 (2.2)	0 (0.0)	1 (1.9)

T0: first round of screening; and T1: second round of screening. [a]Values expressed as n (%). [b]Control stability for 6 months; evolution to Lung-RADS 4 in 1 year, later diagnosed with neoplasia. [c]Includes one case of breast cancer metastasis.

These results are similar to those in international studies, and the authors concluded that the local prevalence of granulomatous diseases did not increase the number of lung biopsies. The results in our study are in the same direction and significantly increased the number of patients screened in the public health care system (401 in Hochhegger et al.[20] vs. 721 in this study). Even with the limitations inherent to the public health care system context, our early staging rates were similar to those of Hochhegger et al.[20] (64.3% vs. 70.3%), which represents a very important advance in relation to the usual rates without screening. We believe that the expertise of large-volume or academic centers in a multidisciplinary context with specialists familiar with the local epidemiology and management of granulomatous diseases can contribute to satisfactory results, such as those obtained in the present study, without unnecessary investigations.

Finally, the rate of loss to follow-up was a significant limitation. This is a constant concern in clinical screening practice in real-life situations.[21] A recent meta-analysis by Lopez-Olivo et al.[22] included 15 American studies (16,863 patients) and found an overall adherence rate of only 55%. The authors[22] found that the following factors had important associations with low adherence: current smoking, ethnic minorities, age < 65 years, low educational level, and decentralized screening programs. In our study, the reasons for the low rate of T1 screenings were not evaluated and may have been due to either the physician's or the patient's decision, which were beyond the scope of this study. However, all positive screenings were carefully reviewed, and our loss to follow-up was approximately 20%. Unfortunately, our retrospective study could not identify causes of nonadherence to the visits or of the failure to carry out the investigations requested after a positive screening. In addition to the usual causes of poor adherence, one possible factor is that some patients with positive screening at the end of 2019 may have had difficulties in scheduling control CTs or medical visits due to restrictions caused by the COVID-19 pandemic (from March of 2020). Although the high rate of patients lost to follow-up is worrisome, we understand that the adherence issues in our study are similar to those reported in real-life studies[22,23] and that detecting such limitations may help improve the program, including strategies to contact missing patients and improve "navigation" after a positive result. We also believe that patients who are already linked to outpatient care may have better adherence to subsequent rounds of screening.

In conclusion, a lung cancer screening program for patients undergoing respiratory follow-up in the Brazilian public health care system in an area with a high incidence of granulomatous diseases and with a high rate of residual inflammatory findings on CT obtained satisfactory results that are comparable to results in other cohorts in different contexts. The high rate of early staging is encouraging and suggests a beneficial impact on the number of treatments with curative intent. The frequency of incomplete investigations after positive screening points to the need for constant monitoring and interventions to ensure adherence to screening.

AUTHOR CONTRIBUTIONS

FMS, MMRL, APGS, RSG, and CFA: conceptualization. FMS, MMRL, and CFA: data curation. FMS and CFA: formal analysis. CTMO, RUB, FMS, RSG, ACC, APGS, and MMRL: investigation. FMS: drafting of the manuscript. FMS, CFA, RSG, MMRL, and APGS: editing and review of

the manuscript. All authors approved the final version of the manuscript.

CONFLICTS OF INtEREST

None declared.

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