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Authors

Kallianos, Kimberly G
Elicker, Brett M
Henry, Travis S
et al.

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Instituting a Low-dose CT-guided Lung Biopsy Protocol

Kimberly G. Kallianos, MD, Brett M. Elicker, MD, Travis S. Henry, MD, Karen G. Ordovas, MD, MAS, Janet Nguyen, MD, David M. Naeger, MD

Rationale and Objectives: We aimed to evaluate whether implementation of a low-dose computed tomography (CT)-guided lung biopsy protocol, with the support of individual radiologists in the section, would lead to immediate and sustained decreases in radiation dose associated with CT-guided lung biopsies.

Materials and Methods: A low-dose CT-guided lung biopsy protocol was developed with modifications of kilovoltage peak, milliamperes, and scan coverage. Out of 413 CT-guided lung biopsies evaluated over a 3-year period beginning in 2009, 175 performed with a standard protocol before the development of a low-dose protocol, and 238 performed with a low-dose protocol. The dose-length product (DLP) was recorded for each lung biopsy and retrospectively compared between the two protocols. Individual radiologist level DLPs were also compared before and after the protocol change.

Results: The mean biopsy dose decreased by 64.4% with the low-dose protocol (113.8 milligray centimeters versus 319.7 milligray centimeters; $P < 0.001$). This decrease in radiation dose persisted throughout the entire 18 months evaluated following the protocol change. After the protocol change, each attending radiologist demonstrated a decrease in administered radiation dose. The diagnostic outcome rate and complication rate were unchanged over the interval.

Conclusions: Implementation of a low-dose CT-guided lung biopsy protocol resulted in an immediate reduction in patient radiation dose that was seen with all attending radiologists and persisted for at least 18 months. Such an intervention may be considered at other institutions wishing to reduce patient doses.

Key Words: Radiation dose; CT-guided lung biopsy; low-dose.

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INTRODUCTION

The last decade has brought increased awareness of the cancer-inducing risks of radiation sustained from medical imaging, and with it, a movement to decrease doses from modalities such as computed tomography (CT) (1–3). CT-guided biopsies can result in high doses by virtue of the repetitive imaging required with some techniques (4); however, biopsies are prime candidates for dose reduction because image quality is less of a concern when used solely for needle guidance.

Previous works have shown the success of low-dose protocols in a variety of procedural settings, including CT-guided spine procedures (5,6) and CT-guided lung biopsies (7–9). However, the previous work with low-dose CT-guided lung biopsies was limited by small sample sizes, relatively short follow-up periods to evaluate dose reductions, and limited analysis of the effect of a standardized low-dose protocol on multiple operators. The present study examines the effect of

a section-wide implementation of a low-dose CT-guided lung biopsy protocol in a high-volume referral center. This analysis includes an evaluation of the radiation doses over time and the radiation dose reductions achieved by individual attending radiologists.

Our hypotheses were that implementation of a low-dose CT-guided lung biopsy protocol with the support of individual radiologists in the section would lead to immediate and sustained decreases in radiation dose associated with CT-guided lung biopsies.

MATERIALS AND METHODS

Low-dose CT-guided Lung Biopsy Protocol

A low-dose CT-guided lung biopsy protocol that included recommendations for multiple aspects of the biopsy including modifications of the kilovoltage peak (kVp), milliamperes (mA), and scan coverage was developed at our institution. Development and implementation of the protocol was reached by consensus of all attending radiologists in the cardiothoracic section at our institution who performed biopsies during both the standard and the low-dose periods ($n = 6$) (10–12). The protocol was divided into three phases of image acquisition for each biopsy: the planning phase, the targeting phase, and the postphase. The technical parameters of this consensus low-dose protocol are provided in Table 1.

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From the Department of Radiology and Biomedical Imaging, University of California, San Francisco, 505 Parnassus Ave., M-391, San Francisco, CA 94143-0628. Received March 22, 2016; revised May 3, 2016; accepted May 4, 2016. Previous submissions/reports of similar type information: None. Grants/funding: Dr. Kallianos is supported by the National Institutes of Health T32 Training Grant, 2T32EB001631-11. **Address correspondence to:** D.M.N. e-mail: David.Naeger@ucsf.edu

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TABLE 1. Low-dose CT-guided Lung Biopsy Protocol*

Phase	Coverage	Slice Thickness	Voltage	Tube Current
Planning	Prior CTs should first be reviewed to select the optimal target. If the selected nodule is visible on the biopsy scout image, then coverage approximately 0.5 cm above and below the lesion is acquired. If the lesion is not visible on the scout, a slightly larger range is acquired based on landmarks from prior CT.	2.5 mm	100 kVP for patient weight <140 lbs and arms up 120 kVP for patient weight >140 lbs and/or arms down	10 mA for scout 40 mA for patient weight <140 lbs and arms up 50 mA for patient weight >140 lbs and/or arms down 60 mA for patient weight >220 lbs and/or lesion at level of the liver
Targeting	Nine images per iteration, then seven images per iteration, then five images per iteration if possible	2.5 mm	100 kVP for patient weight <140 lbs and arms up 120 kVP for patient weight >140 lbs and/or arms down	20 mA for patient weight <140 and arms up 25 mA for patient weight >140 and/or arms down 30 mA for patient weight >220 and/or lesion at level of the liver
Post	Limited or whole chest	5 mm	100 kVP for patient weight <140 lbs and arms up 120 kVP for patient weight >140 lbs and/or arms down	20 mA for patient weight <220 lbs 30 mA for patient weight >220 lbs

CT, computed tomography; kVP, kilovoltage peak; mA, milliamperes.

* Typically using sharp reconstruction algorithm.

All CT-guided lung biopsies were performed on either a LightSpeed VCT or Discovery HD 750 (GE Healthcare, Milwaukee, WI). The same parameters were generally used on both scanners; adaptive statistical iterative reconstruction was not used. A standard coaxial technique was used for lung biopsies with a 19-gauge coaxial needle followed by 20–22 gauge fine needle aspiration (FNA) needles and 20-gauge core biopsy needles. The average number of samples per patient was 3.2, predominately FNA (average FNA samples 2.7 per patient versus average core biopsy samples 0.5 per patient). Feedback from an on-site pathologist was the main factor in determining the number and type of samples required. Biopsies were deemed diagnostic when the final pathologic analysis could establish a diagnosis of a *specific* benign entity or malignancy from the material obtained.

Retrospective Data Collection

Our institutional review board approved the creation of a Health Insurance Portability and Accountability Act compliant database of CT-guided lung biopsies. All CT-guided lung biopsies performed during a 36-month period from September 2009 to August 2012 were included in the dataset. The dataset was divided into two groups: those undergoing biopsy in the 18 months before the protocol change (the standard-dose group), and those undergoing biopsy in the 18 months after the protocol change (the low-dose group). Biopsies for which CT dose reports were not available were excluded. For all included biopsies, the following data were extracted:

- Patient age
- Attending radiologist
- Lesion long axis size
- Lesion depth from the pleura
- Severity of emphysema (mild, moderate, and severe)
- Number of biopsy specimens obtained
- Presence of biopsy complications: pneumothorax, chest tube placement, serious hemorrhage, and death
- Radiation dose
- Total coverage scanned, summed for all series (cm)
- Total number of series performed

Radiation dose data were recorded in the form of dose-length product (DLP), which is the product of scan length in centimeter and the volume CT dose index for each individual scan event. Given that each scan event can vary in the length covered and in the volume CT dose index, DLP acts as a summary measurement. DLP is measured in milligray centimeter (mGy-cm) (13,14).

For the purposes of analyzing radiation doses, the CT-guided lung biopsies were separated into three phases: planning, targeting, and post. The planning phase was defined as the initial CT acquisition(s) with a surface grid in place for lesion localization and selection of a needle path. The targeting phase was defined as the multiple acquisitions in which the needle was advanced into the lesion, and biopsy samples were obtained. The post phase was defined as the CT acquisition after the needle was removed, which was used to evaluate for the presence of biopsy complications such as pneumothorax (15). Radiation dose (DLP), total coverage (cm), and total number of series were recorded for each of the three phases. When

multiple acquisitions were performed during a single phase, the scan coverage and DLP for each individual acquisition were summed.

Radiation doses (DLP) were also tabulated for each of the six attending radiologists who performed lung biopsies both before and after the protocol change. There was no systematic difference in the difficulty of biopsies performed by various attending radiologists because the attending radiologist assigned to biopsies each day was responsible for all scheduled procedures, regardless of difficulty, and the scheduling process did not take into account the attendings assigned to be on service on any given day. For the purposes of data presentation, radiologists were ordered based on the highest to lowest initial radiation doses.

The diagnosis of a postprocedure pneumothorax was made with a post phase CT, or via a standard postbiopsy chest radiograph that was obtained before discharge.

Statistical Analysis

Data analysis was performed using Stata version 14.0 (College Station, TX). Summary statistics are reported as medians and interquartile ranges (IQR). Continuous parameters before and after the protocol change were compared using Mann-Whitney *U* tests due to non-normally distributed data. Chi-squared tests were used to test for equality between proportions. Comparison of continuous parameters over successive 6-month periods surrounding the protocol change was performed with the Kruskal-Wallis equality-of-populations rank test. Statistical significance was set at $P < 0.05$.

RESULTS

A total of 446 biopsies were performed during the study period, and 33 (7.4%) were excluded because CT dose reports were not available: 27 from the standard-dose group and 6 from the low-dose group. Out of 413 CT-guided lung biopsies included in our study, 175 performed with the standard protocol and 238 performed in the period after which the low-dose protocol was instituted. Of note, overall imaging and procedure volume increased at our institution over the study period.

There was no significant difference in patient-specific parameters between the two groups including age, gender (Table 2A), as well as severity of emphysema (57.7% none, 17.7% mild, 17.1% moderate, 7.4% severe with the standard protocol versus 47.5% none, 18.5% mild, 25.2% moderate, and 8.8% severe with the low-dose protocol, $P = 0.150$). Lesion-specific parameters were also not significantly different between the standard and the low-dose biopsy protocols including lesion long axis size of 4.0 ± 2.5 cm versus 3.8 ± 2.7 cm ($P = 0.231$) and lesion depth from the pleura of 1.8 ± 1.8 cm versus 2.1 ± 2.2 cm ($P = 0.185$).

Total biopsy dose decreased an average of 64.4% under the low-dose protocol compared to the standard protocol (DLP 113.8 mGy-cm versus 319.7 mGy-cm; $P < 0.001$).

Moreover, statistically significant dose reductions were observed in all three phases of the biopsy (77.4%, 52.3%, and 65.8% for the planning, targeting, and postbiopsy phases, respectively). Figure 1 depicts representative CT-guided lung biopsy images using the standard versus the low-dose protocols.

The largest contributor to patient radiation dose using the standard-dose protocol was the planning phase with median DLP of 142.4 mGy-cm [IQR 51.7–917.9], whereas the largest contributor to patient radiation dose using the low-dose protocol was the targeting phase, median DLP 39.3 mGy-cm [IQR 23.5–60.6].

The total number of series used to complete the biopsies significantly increased after the protocol change, median 12 [IQR 9–15] with the low-dose protocol compared to a median 9 [IQR 7–12] with the standard-dose protocol ($P < 0.001$) (Table 2A). Total coverage in centimeters was not significantly different ($P = 0.149$); however, there was a significant decrease in coverage during the planning phase specifically (median 122.5 cm with the low-dose protocol versus a median 156.3 cm with the standard protocol) when analyzed alone, $P < 0.001$.

To further delineate trends over time, the information in Table 2A was subdivided into six 6-month periods (Table 2B, Fig 2). Radiation dose was relatively stable in the 18 months before the protocol change, and immediately decreased in the 6-month period afterward. This immediate decrease in radiation dose persisted throughout the subsequent two 6-month periods following the protocol change, thereby demonstrating 18 months total of reduced doses.

Biopsy radiation doses using the standard protocol and low-dose protocol were evaluated at the individual attending radiologist level. After the protocol change, each attending radiologist demonstrated a decrease in the radiation doses used (Fig 3). This decrease was statistically significant for three attendings (#1, 2, and 5). Before the protocol change, there was a large range of radiation doses used between attending radiologists; the difference from the lowest to the highest median radiation doses was 387.9 mGy-cm. Afterward, radiation doses fell within a narrower range of 122.3 mGy-cm between the highest and lowest attending's medians, a 68.5% decrease in the range of medians.

After the protocol change, there was a non-statistically significant trend toward a decrease in pneumothorax rate: 64/238 (26.9%) using the low-dose protocol compared to 57/175 (32.6%) using the standard-dose protocol ($P = 0.210$). There was also a trend toward the decrease in a chest tube placement rate: 16/238 (6.7%) using the low-dose protocol compared to 21/175 (12.0%) using the standard-dose protocol compared ($P = 0.064$). There was no significant difference in rates of serious hemorrhage between the two protocols: 1/175 versus 1/238, $P = 0.827$. There were no patient deaths with either protocol.

A diagnostic result (eg a pathologic diagnosis of cancer, infection, or a specific benign pathology) was achieved in 182/238 (76.5%) with the low-dose protocol and 137/175 (78.3%) with

TABLE 2. (A) Radiation Dose before and after the CT-guided Lung Biopsy Protocol Change. (B) Radiation Dose over 6-month Periods Surrounding Protocol Change, Median [IQR]

(A)

	Standard-dose Protocol (n = 175) Median [IQR]	Low-dose Protocol (n = 238) Median [IQR]	Percentage Change (%)	P Value (Mann-Whitney U)
Age (years)	67 [58–76]	66 [60–75]	NA	0.803
Male (%)	114/175 (65.1%)	163/238 (68.5%)	NA	0.475
Total DLP (mGy-cm)	319.7 [156.1–872.9]	113.8 [66.1–187.8]	–64.4	<0.001
Total coverage (cm)	492.5 [367.5–647.5]	467.5 [345–587.5]	–5.1	0.149
Total series #	9 [7–12]	12 [9–15]	+33.3	<0.001
Planning				
DLP (mGy-cm)	142.4 [51.7–317.9]	32.2 [15.5–72.9]	–77.4	<0.001
Coverage (cm)	156.3 [112.5–225]	122.5 [90.5–175]	–21.6	<0.001
Series #	1 [1–2]	2 [1–2]	+100.0	0.001
Targeting				
DLP (mGy-cm)	82.4 [34.0–282.2]	39.3 [23.5–60.6]	–52.3	<0.001
Coverage (cm)	142.5 [75–225]	140 [90–221.5]	–1.8	0.643
Series #	6 [4–9]	9 [6–12]	+50.0	<0.001
Post				
DLP (mGy-cm)	62.1 [23.4–208]	21.2 [12.4–42.7]	–65.9	<0.001
Coverage (cm)	165.6 [82.5–260]	190 [100–260]	+14.7	0.495
Series #	1 [1–1]	1 [1–1]	0.0	0.007*

(B)

	12–18 Months before (n = 46)	6–12 Months before (n = 56)	6 Months before (n = 73)	6 Months after (n = 89)	6–12 Months after (n = 78)	12–18 Months after (n = 71)	P Value (Kruskal-Wallis)
Total DLP (mGy-cm)	284.5 [165.7–859.2]	400.0 [193.3–1080.1]	309.2 [110.0–782.1]	102.3 [70.0–148.4]	120.8 [64.9–214.2]	117.8 [59.9–202.5]	<0.001
Planning							
DLP (mGy-cm)	118.6 [57.8–354.8]	178.4 [65.8–342.9]	144.8 [38.4–277.9]	31.7 [19.2–63.7]	34.2 [13.5–74.7]	31.6 [16.0–79.2]	<0.001
Coverage (cm)	162.5 [132.5–240]	165.3 [110–223.4]	150 [100–202.5]	122.5 [90–170]	132.5 [92.5–192.5]	115 [90–162.5]	<0.001
Series #	1 [1–2]	2 [1–2]	1 [1–2]	2 [1–2]	2 [1–2]	2 [1–2]	0.002
Targeting							
DLP (mGy-cm)	93.2 [38.6–339.4]	67.0 [37.3–504.3]	83.6 [30.4–220.6]	34.7 [22.3–59.8]	40.5 [22.2–60.2]	42.3 [24.3–73.5]	<0.001
Coverage (cm)	125 [75–245]	143.8 [72.5–232.5]	150 [90–210]	150 [90–225]	143.8 [100–221.5]	115 [70–200]	0.436
Series #	6 [4–10]	6 [4–9.5]	7 [5–9]	9 [6–10]	9 [6–12]	9 [6–13]	<0.001
Post							
DLP (mGy-cm)	67.3 [28.8–204.3]	104.5 [36.9–264.2]	37.3 [20.3–180.5]	20.8 [11.6–35.3]	29.0 [13.7–61.0]	19.7 [11.8–40.6]	<0.001
Coverage (cm)	147.5 [50–245]	169 [95–270]	166.3 [90–277.5]	197.5 [98.1–260]	205 [115–272.8]	157.5 [80–262.5]	0.317
Series #	1 [1–1]	1 [1–1]	1 [1–1]	1 [1–1]	1 [1–1]	1 [1–1]	0.109

cm, centimeter; DLP, dose-length product; IQR, interquartile range; mGy, milligray.

* Despite unchanged median and IQR, the distribution of biopsies with >1 # of series differed between the two groups.

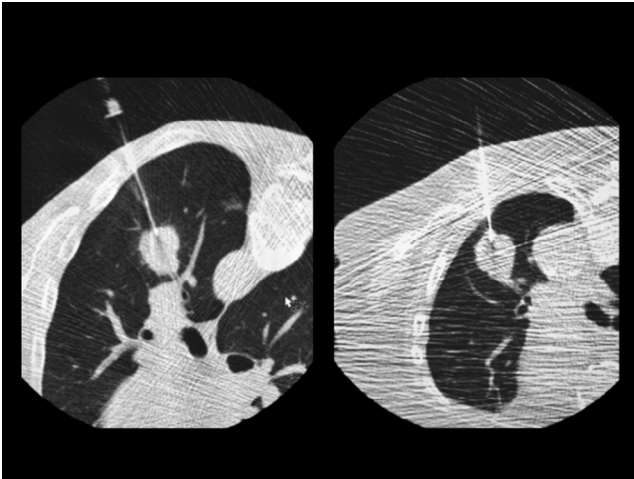


Figure 1. Representative biopsy images using the standard-dose protocol (left, total DLP = 568.12) and the low-dose protocol (right, total DLP = 16.33). DLP, dose-length product.

the standard dose, $P = 0.664$. There was a statically significant increase in the number of biopsy samples obtained with the low-dose protocol (3.5 ± 2.0 samples) compared to those of the standard-dose protocol (2.8 ± 1.9), $P < 0.001$.

DISCUSSION

We instituted a low-dose CT-guided biopsy protocol in our busy lung biopsy service that provided general guidelines for dose reduction techniques. The resultant effect of such a policy was a decrease in radiation dose overall, and for each individual attending, with no change in the complication and non-diagnostic biopsy rates. This effect was sustained for the 18 months evaluated after the protocol change.

Our low-dose CT-guided lung biopsy protocol included recommendations for multiple aspects of the biopsy including modifications of the kVp, mA, and scan coverage (1,10–12). The recommendations to reduce CT coverage did not result

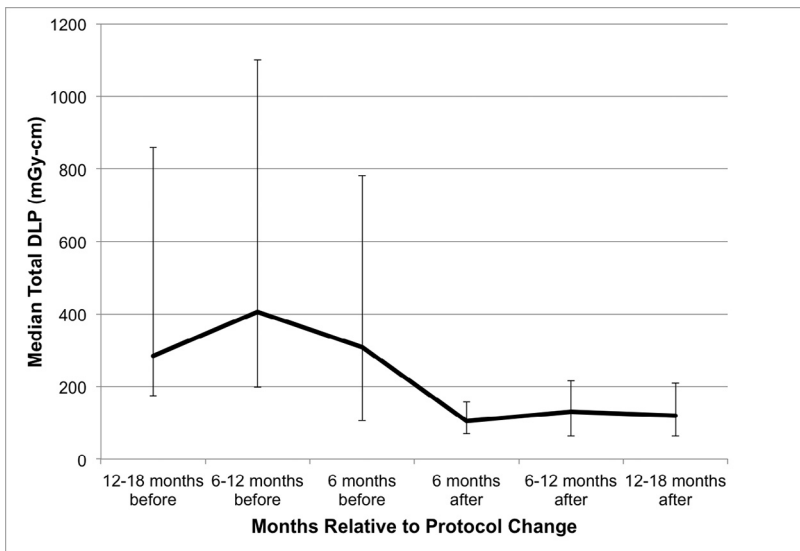


Figure 2. Graphical representation of total DLP over 6-month periods surrounding the protocol change. The *thick line* represents median DLP, with the upper and lower *whisker lines* representing the interquartile range. Kruskal-Wallis test for differences, $P < 0.001$. DLP, dose-length product.

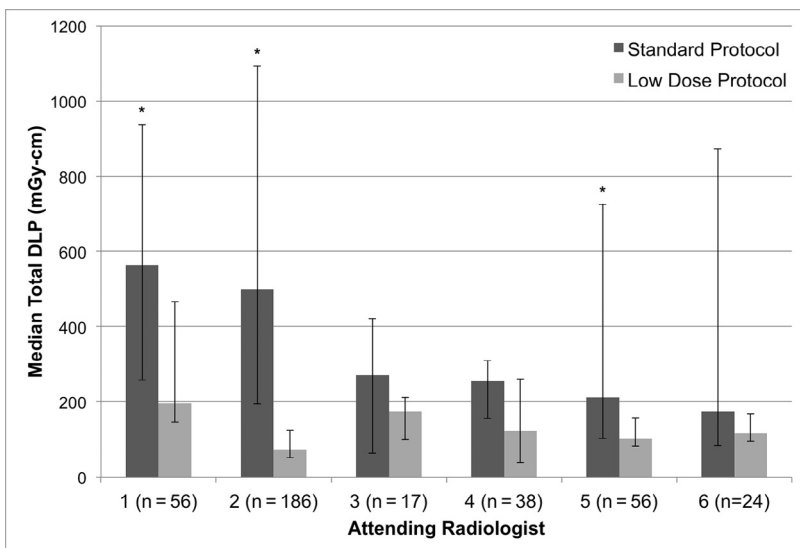


Figure 3. Total DLP by attending radiologists before and after the protocol change. The *bars* represent median DLP, with the upper and lower *whisker lines* representing the interquartile range. Statistically significant difference at the $P = 0.05$ level is denoted by an asterisk. The attending radiologists are presented in order from the highest to the lowest median radiation doses used before the intervention. DLP, dose-length product.

in a statistically significant change in overall coverage; however, there was a mild, statistically significant reduction in coverage during the planning phase when analyzed alone. Interestingly, there was a significant *increase* in the number of series performed during biopsies following the protocol change. The cause of the increase in series number was not directly investigated; however, smaller coverage field may have been a contributing factor. Given that coverage and the series number did not dramatically decrease, the majority of the decrease in radiation dose achieved by our low-dose CT-guided lung biopsy protocol was the result of decreased exposures parameters (lower mA and/or kVP).

Although radiation dose reduction was achieved in all phases of the biopsy, the greatest decrease in dose was seen in the planning phase. As a result, the targeting phase imparted the largest median radiation dose after the protocol change.

Prior studies of low-dose lung biopsies have focused on technical success and complication rates following low-dose CT-guided biopsies. Similar to these studies, we did not observe a significant change in the percentage of biopsies achieving a diagnostic result following implementation of a low-dose protocol. We did observe a lower overall diagnostic biopsy rate, both before and after the protocol change, compared to the range reported in prior studies of 92%–95.8%, which may be related to our classifying nonspecific pathologies such as inflammation as “non-diagnostic” (16). Additionally, our group is asked to attempt biopsies on small lesions (<1 cm) in cases where the possible clinical benefit outweighs the increased risk of a non-diagnostic result. The complication rates reported in the literature ranging from 10% to 32% were similar to the complication rates observed in our low-dose group (7–9), and complication rates did not increase at our institution over this interval (indeed, slightly lower complication rates were observed, likely unrelated to the change in biopsy protocol). Our protocol allowed for flexibility in the CT parameters depending upon patient-specific factors and the preferences of the attending radiologists. Despite this flexibility, our median radiation dose of 113.8 mGy-cm falls within the range reported in the literature (10.98 mGy-cm to 133.3 mGy-cm) with our overall dose reduction of 64.4% also within the range of dose reductions reported in the literature of similar interventions (57.5%–95%) (7–9).

To our knowledge, there has been no previous investigation of low-dose CT-guided lung biopsies that included an assessment of long-term reductions in radiation dose. Our study demonstrated a dramatic effect that was seen within the first 6 months and that persisted for the full 18 months evaluated after the protocol change. This confirms that a low-dose CT-guided biopsy protocol can be successfully implemented with a sustained reduction in the doses used. In addition, our study is the first to perform analysis of CT-guided lung biopsy dose reduction at the individual attending radiologist level. In our section, all radiologists had a reduction in their radiation doses following the protocol change, three of which were statistically significant. Despite individual differences in biopsy technique, our data suggest that interventions such as this can

result in broad changes, standardizing the radiation dose of CT-guided lung biopsies and reducing variability between radiologists. Finally, whereas other studies have also evaluated overall radiation dose reduction, we additionally assessed which phases were most impacted by dose reduction techniques, specifically the planning phase.

This study has several limitations. First, our biopsies were performed by a single group of attending radiologists at one institution. Additionally, although we followed radiation dose for 18 months after the protocol change, further long-term follow-up could be performed to confirm continued success. The present study employed a retrospective design; therefore, prospective data gathering and randomization were not possible. We were not able to collect data on procedure duration as a part of this analysis; however, we included a number of biopsy samples collected as a proxy for procedure length. Of note, there was a statistically significant increase in the number of samples obtained under the low-dose protocol compared to that under the standard protocol, a large component of which is likely related to the increased use of molecular testing, which requires additional samples. We suspect that this effect is not related to the radiation dose protocol change; however, the lack of data on true procedure duration limits our ability to fully explore this finding. Although specific care was taken to maintain the quality of the postbiopsy scans to detect complications, the slightly lower pneumothorax detection rate on the postscans could be due to a lower sensitivity. Postprocedure radiographs, which were used in both protocols, should have ensured similar sensitivities for clinically significant pneumothoraces.

CONCLUSIONS

In summary, implementation of a low-dose CT-guided lung biopsy protocol at our institution resulted in an immediate reduction in patient radiation dose, which was seen by all attending radiologists and persisted for at least 18 months. The results of the present study suggest that low-dose CT-guided lung biopsy protocols can be successfully implemented in real-world radiology practices. Awareness of the success of such an intervention is important for radiologists seeking to reduce patient radiation dose associated with their CT-guided lung biopsies.

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