

DOI: 10.21767/2471-8564.3.1.2

CT-Fluoroscopy versus Conventional Helical CT Guidance for Lung Biopsies Performed By Clinical Fellows without Prior Training: Radiation Dose and Workflow

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Received date: December 4, 2019; Accepted date: February 10, 2020; Published date: February 17, 2020

Citation: Kandel S (2020) CT-fluoroscopy versus conventional helical CT guidance for lung biopsies performed by clinical fellows without prior training: radiation dose and workflow. J Imaging Interv Radiol Vol 3 No.1:2. DOI: 10.21767/2471-8564.3.1.2

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Abstract

Purpose: To analyse the impact of CT-fluoroscopy versus conventional CT-guidance in lung biopsies, performed by radiologists (clinical fellows) without prior CT-fluoroscopy experience, on radiation dose and navigation time.

Material and Methods: Ninety-one consecutive patients referred for CT-guided chest biopsies within the first half of the academic year were retrospectively analysed. All biopsies were performed by three clinical fellows who had pre-existing experience with conventional CT-guided biopsies but were novices to CT-fluoroscopy guidance. Needle navigation was guided by helical CT mode in 45 patients (Group I) and by CT fluoroscopy in 46 patients (Group II). Patient age, gender, lesion size, site of the lesion, depth (skin to lesion, pleura to lesion), complications, navigation time and DLP were recorded and statistically compared.

Results: Mean patient radiation dose (DLP, mGy*cm) was 76.12 (SD: 57.72) in Group I (~ 1.29 mSv) and 59.59 (SD: 36.28) in Group II (~1.01 mSv) ($p=0.05$). Navigation time of 21 min (SD: 14) in Group I was significantly longer than 12 min in Group II (SD: 9) ($p=0.0004$). All other parameters did not show significant differences between the two groups.

Conclusion: CT-fluoroscopy guidance in lung biopsies performed by fellows leads to shorter navigation time and lower radiation dose to the patients.

Introduction

Computed tomography (CT) guided chest biopsies have been integrated into clinical practice as a standard procedure to obtain samples from pulmonary nodules and mediastinal lesions for tissue diagnosis. The two most commonly used methods are CT-fluoroscopy (CTF) and CT helical (CTH) mode guidance [1-3]. CTF allows for real time monitoring of the needle during the biopsy procedure and can be applied both continuously and intermittently. CTF has been shown to decrease both the procedure time and complication rate [4-6]. The literature regarding the radiation dose to patients is controversial. Some authors report higher doses when compared to biopsies performed under CT helical mode guidance [7,8]; others report a relative dose reduction [9,10]. However, the performing radiologist's exposure to radiation is higher in CTF as the operator remains in the room at the time of CT scanning [11]. To the contrary, radiation exposure to the operator does not exist with CT helical mode guidance when the operator leaves the room during helical data acquisition. Going in and out of the scan room may be tedious, leaves the patient alone on the table possibly with a needle on its way to the target, and can increase the procedure time [12].

As in most interventional procedures the radiation dose and procedure time may, to a certain extent, depend on the experience of the performing operator [13]. The aim of our study was to analyse the difference in radiation exposure and needle navigation time between CTF and CTH guidance of chest biopsies performed by fellows who are inexperienced in using CTF guidance.

Keywords: Navigation time; Radiation dose; Fellows; Lung; Biopsy

Abbreviations

CTH: CT helical; CTF: CT-fluoroscopy; ROSE: Rapid on site evaluation; EPR: Electronic patient record

Materials and Methods

This retrospective study was approved by our institutional ethics review board. During the first half of the academic year (July-December) a total of 102 consecutive patients underwent a lung biopsy using CT guidance in our Department. All patients were referred for a CT guided lung biopsy as part of their clinical workup. All procedures were performed by three clinical fellows

who had undergone baseline hands-on training in CT guided biopsies as part of their residency programme, but were novices in using CT-fluoroscopy techniques. All patients were booked by a central booking office solely based on patient preference and schedule availability from Monday through Friday. Biopsies were approved prior to booking by the attending staff radiologist based on existing internal or outside prior CT images. All biopsies were performed by the clinical fellows under supervision by the attending staff radiologist assigned to the service on that day. The clinical schedule both for fellows and staff radiologists was made weeks in advance, these cases were not specifically assigned to any operator (fellow or supervising staff radiologist).

At the beginning of their fellowship, the fellows were instructed to become acquainted with both CT guidance techniques as part of their clinical training program, supported by all six staff radiologists. The decision as to the CT guidance technique was exclusively left with the fellow who was assigned to biopsy service on a rotating schedule, and varied on a daily basis.

CT Protocol and technique

All biopsies were performed on a Toshiba 64-slice scanner (Toshiba Aquilion 64, Toshiba Medical Systems, Nasu/Otawara, Japan). The unit was measured by the institutional Radiation Protection Officer and approved for clinical use. Scatter exposure for an operator in 100 cm distance to the point of entry was 0.001 mSv/s based on a 8 mm slice thickness, 32 cm water phantom, 120 kV and 50 mA, and 0.5 s rotation time.

Patients were put in feet-first prone, supine, lateral or decubitus position on the CT table based on the assumed best approach and our standard of care process. The best approach was clinically defined as follows: shortest possible skin to lesion distance, while avoiding visible bullae and crossing fissures if at all possible.

An initial scout and low dose helical CT (120 kV, 30 mA) without breath-holding for planning purposes were acquired for every case. After localisation of the target lesion, the access path was measured on the corresponding CT-slice and the intended entry point of the biopsy needle was marked on the patient's skin accordingly using the integrated laser beam.

If CT-fluoroscopy was the chosen method for guidance, the scanner was exclusively operated in the intermittent mode in which a single axial slice was being acquired and immediately reconstructed and displayed, initiated by the performing operator in the room. The parameter setting for CTF was 30-50 mA, 120 kV, 0.5 sec rotation time, slice thickness 4 mm. Images obtained during the procedure confirming the path of the needle, were displayed as a single image on a LCD monitor (1024 × 768 pixels, size 30.4 × 22.8 cm) in the CT suite. All images were stored as displayed to the operator and stored in the PACS for later review.

All fellows were instructed to strictly avoid direct exposure of their hands to the primary X-ray beam. If holding the needle was required, a standard surgical clamp was used while the hands were at least 20 cm away from the scan plane. Images were

acquired with a foot pedal while table position was controlled by the radiologist using the table handle under sterile conditions (floating table).

If the conventional CT helical technique was chosen as the guidance method, several short 3 cm helical scans were acquired over the area of the expected needle position during which the operator left the scanning room and observed the reconstruction on the CT console. CT helical parameters were: 30-50 mA, 120 kV, rotation time of 0.5 sec, reconstruction slice thickness of 3 mm.

At the end of the biopsy procedure, a low dose CT (120 kV, 10 mA) of the whole chest was performed to exclude possible complications. Chest radiographs in upright position were obtained after 1 hour. Follow up chest radiographs after 2 hours were acquired if the patient was older than 70 years or the post biopsy CT showed a pneumothorax. The decision to drain a pneumothorax was made by the fellow and supervising staff.

All radiologists who remained physically present in the scanner room during CT fluoroscopy data acquisition mandatorily wore certified whole-body lead aprons and thyroid protection, both with more than 95% absorption rate (0.5 mm lead equivalent in front, 0.3 mm lead equivalent in the back of the apron), and were monitored with film dosimeters (worn under the apron) according to the regulatory framework. Finger ring dosimeters were not used.

Biopsy technique

CT biopsies were performed using a 19-gauge co-axial introducer needle (Bard R Truguide) with a 22-gauge Chiba biopsy needle (COOK) for fine-needle aspiration (FNA). All FNA samples were assessed for adequacy by a cytopathologist and cytotechnologist (Rapid On Site Evaluation, ROSE). Core samples were obtained using a 20-gauge cutting needle (Care Fusion) when the FNA samples were deemed inconclusive by the onsite cytopathologist or in case of suspected lymphoma. When performed, the core samples were fixed in 7.5% formalin solution for histopathology analysis.

Data collection and statistical analysis

Patient age, gender, lesion size, site of the lesion, depth (skin to lesion, pleura to lesion) and navigation time were obtained using the PACS, RIS and electronic patient record (EPR) systems. Navigation time was defined as the time between the first image showing the needle in the skin to the time when the coaxial needle was in its desired position at the edge or within the lesion prior to FNA sampling, the time stamps were taken from the respective DICOM images. Radiation dose of CTF and CTH procedures was calculated from the dose-length-products (DLP.e) listed on the patient summary sheet multiplied by the factor of 0.017 [14]. Post lung biopsy complications such as pneumothorax, placement of a chest drain and parenchymal haemorrhage were recorded. Cytology and histopathology data was divided into the following diagnostic categories: malignancy, suspected malignancy, negative for malignancy, and non-diagnostic (necrosis or cell paucity). Malignancy or suspected malignancy designations were considered as positive results. All

cases in which the pathology results were unsatisfactory for evaluation or necrotic were considered negative. A per-operator analysis was conducted in order to assess differences in performance between the three fellows (Fellow 1,2,3).

Data was analysed with Excel (Microsoft Office Professional Plus 2010 version: 14.0.4760.1000). Values were tested for normal distribution using the KS-test and comparison was made by using the unpaired t-test, Chi-Square test and Fisher's exact test for contingency tables. P-values ≤ 0.05 were considered to indicate statistically significant differences.

Results

Out of 102 patients, 11 patients had to be excluded due to missing data on radiation dose or prolonged procedure time related to non-biopsy related complications during the interventions, resulting in a total of 91 patients who were finally included in the analysis. Needle navigation was performed by CTH mode in 45 patients (20 women and 25 men) (Group I) and by CTF in 46 patients (21 women and 25 men) (Group II). The median age of the patient population was 64.5 years in Group I and 60 years in Group II ($p=0.15$).

Mean patient radiation dose for Group I and II was 76.12 (mGy*cm) (SD: 57.72) (~ 1.29 mSv) and 59.5 (mGy*cm) (SD: 36.28) (~ 1.01 mSv) with normal distribution in both groups, and was significantly lower in Group II than in Group I ($p=0.05$). Group I had a statistically significant longer navigation time than Group II ($p=0.0004$) with a duration time of 21 min (SD: 14) and 12 min (SD: 9) in Group II.

There was no statistically significant difference of the mean lesion size, mean depth of lesion from the pleura and mean skin to pleural depth between the two groups (**Table 1**). The sites of the target lung lesions in either group are shown in **Table 2**; there was no statistical difference in the table ($p=0.24$).

Table 1: CTF versus CTH guided trans-thoracic biopsies: Mean lesion size, pleura to lesion depth, skin to pleura depth, pathology results and complication rates.

	CTH Group (Fellow 1,2,3)	CTF Group (Fellow 1,2,3)	P val ue
Lesion size (cm)	2.5	2.1	0.3 3
Pleura to lesion depth (cm)	2.05	2.2	0.7 9
Skin to pleura (cm)	3.9	4.3	0.1 6
Pathology Positive:	33	42	0.0 3*
Malignant	32	40	1.0 0*
Benign	1	2	1.0 0*
Negative (Unsatisfactory or Necrotic)	12 (7,4,1)	4 (1,1,2)	0.0 3*

Total	45 (16,16,13)	46 (16,17,13)	
Pneumothorax	12 (3,4,5)	14 (3,6,5)	0.8 1
Pulmonary haemorrhage	0	0	n.a .
*Fisher exact test			

Group II demonstrated a significantly higher diagnostic accuracy rate than Group I ($p=0.03$) predominantly due to the lower number of negative biopsies performed by Fellow 1, with 91% positive results in comparison to 71% in Group I. Pathology results are summarised in **Table 1**.

None of the patients in either group had pulmonary haemorrhage that needed prolonged monitoring or in-patient care. 12 patients in group I and 14 patients in group II developed a pneumothorax after the intervention and there was no statistical difference ($p=0.81$) between the two groups.

In none of the images obtained during CT fluoroscopy procedures were the operator's hands seen, confirming that the initial instruction to the trainees were strictly followed. All three fellows performed an equal number of biopsies (group I/II: Fellow 1, 16/16; Fellow 2, 16/17; Fellow 3, 13/13).

Discussion

CT-fluoroscopy (CTF) refers to the technical ability of the CT unit to provide instant image reconstruction and last image hold on an in-room monitor while the operator is in direct control of the table position and scan initiation. In contrast to the conventional method of acquiring short helical scans over the assumed needle position while the operator typically leaves the scanning room, the CT-fluoroscopy functionality allows the operator to obtain almost immediate (real-time) confirmation of the needle position or its relative position to the target or other anatomical landmarks. If only a single image is being obtained each time the in-room scan button is pressed (typically a foot switch), the mode of using CT fluoroscopy is termed "intermittent" or "quick-check", whereas continuous scanning with real-time reconstruction and dynamic image display is referred to as "continuous mode".

In our study, board certified clinical fellows who were novices to the use of CT-fluoroscopy for lung biopsies, but have had some pre-existing experience with diagnostic biopsies in general, were able to perform lung biopsies faster and with less radiation dose to the patient by using CT fluoroscopy compared to using the conventional technique. In the hands of experienced interventionalists, CT-fluoroscopy has been shown in several studies to be faster and to require fewer needle passes than conventional CT-guiding techniques. Also, study data indicate that the use of CT-fluoroscopy leads to decreased procedure time [4-6,12,15]. Direct comparisons between the two guiding techniques are however difficult because the definition of procedure time differs quite widely amongst the studies. In our study, CT-fluoroscopy guided procedures required on average 9 minutes less for navigating the needle into the target compared to the procedure performed with conventional

CT guidance. The gain in time is mainly attributed to the ability in the CT-fluoroscopy mode to move the table by hand to the target position, the lack of programming delays for short helical scans caused by the user interface and motoric table motion, and the instant availability of the image for review while the patient is still at the target position allowing for immediate intervention or needle correction if necessary. Needle navigation may at times be performed within a single breath-hold which may eliminate numerous attempts to hit the target particularly with smaller nodules.

Radiation exposure due to CT examinations has become a topic of increasing concern in the medical community and in the general population [16,17]. CT-guided interventions are reported to be associated with considerably high effective doses to the patients [18,19]. This is especially true for CT-fluoroscopy guided interventions where, in addition to the patient, the personnel performing the intervention may also be exposed to ionising radiation [7]. Experience with interventions and familiarity with the guidance technique have been shown to be pivotal to reducing both navigation time and radiation dose associated with the procedure [20]. Gianfelice et al. demonstrated that navigation time and radiation dose in CT-fluoroscopy can be decreased by about 50% solely through gaining experience with this novel technique [13]. A wide spectrum of radiation doses to the patient has been reported in the literature, typically ranging from 0.5 to 20.4 mSv [8,12,21,22]. In the hands of fellows in our study, conventional CT guidance was associated with a radiation dose equivalent to approx. 1.3 mSv and CT-fluoroscopy with approximately 1.0 mSv. Both values lie at the lower end of the reported spectrum of reported radiation doses in diagnostic interventions.

Exceedingly high exposure values may result in cases where CT-fluoroscopy is applied in the continuous mode which has led to some concern with this mode being in the hand of unexperienced operators. Nawfel et al. have shown that patients received 830 mGy to the skin during an 80-second continuous CT fluoroscopic exposure [23]. Although 830 mGy skin dose is still less than the often-quoted 2,000 mGy threshold for inducing radiation dermatitis, the value approaches the level of 1,000 mGy at which radiation-induced skin changes have been reported [24]. Most recently, regulatory bodies in several countries mandate that dose limits with respective alerts be implemented by the CT manufacturers, and that specific user authorization becomes mandatory to overrule the alerts on a by case basis.

In our study, continuous mode was never applied but remained available during the intervention in case navigation would become otherwise impossible. Furthermore, all fellows never exposed their hands to the direct X-ray beam. Radiation dose to the operator mainly originates from scattered radiation which is determined by many factors, largely by the tube settings and beam characteristics, slice thickness, patient diameter, tube-skin distance, and availability of angular beam modulation [23]. Reported values of radiation dose to the operator range between 0.007 and 0.048 mSv per procedure, or 0.005 and 0.11 mSv per second [25]. Although we did not measure the radiation dose to the operator's hand in our study,

we assume that similar to the low level of exposure values to our patients, the dose to the operator's hand was likely at the lower end of the reported spectrum as well.

Procedures specifically performed by one clinical fellow under CT-fluoroscopy guidance yielded significantly fewer unsatisfactory pathology results than performed under conventional guidance. Interpretation of this is not intuitive as all demographic parameters were equally distributed between both groups, and the assignment of trainees to the biopsies was random. One possible explanation is that due to the shorter navigation time and the ability to correct the needle position with very little effort and with instant positioning control, the final position of the needle tip within the biopsy target prior to sampling was closer to the ideal position than it was in the group with conventional guidance, however we did not specifically analyse the accuracy of the needle position in either group.

There were important limitations in our study. Firstly, this is a retrospective study and thus we did not prospectively randomize the patients to either group. As a result, it cannot be entirely excluded that personal preference of the performing radiologist, certain imaging features such as lesion size and location, or even the patient's wish might have influenced the decision as to which guidance technique was applied. However, not only did we find an almost equal number of patients in either group, we also did not detect any difference between both groups in regards to the suspected or potentially influential parameters. Secondly, we did not assess the number of passes that were required to obtain sufficient material as assessed by the on-site cytologist. Because the difference between Group I and II was only the method with which the needle was monitored and guided, the possible influence on sampling success once the needle is within the target may be remote. Thirdly, we estimated the radiation dose to the patients by using the DLP.e as displayed on the dose summary sheet. This is a commonly accepted method and we did not attempt to objectivise the values given by the manufacturer. We also did not assess the radiation dose to the operator which is likely negligible if adequate and state-of-the-art protection is applied. Lastly, we did not assess a potential learning curve. It is well possible that progressing experience with handling the CT-fluoroscopy technique may have influenced the navigation time and possibly even the sampling accuracy. However, increased experience would have improved the navigational skills in both groups and may not have necessarily biased the results towards either technique.

Conclusion

In conclusion, our study showed that in the hand of fellows, CT-fluoroscopy for lung biopsies lowered the radiation dose to the patients, shortened the navigation time, and improved the diagnostic accuracy when compared to the use of conventional CT guidance technique. Based on the results of this study, CT-fluoroscopy may be regarded as the preferred method not only in the hands of experienced interventionalists, but also for fellows or novices in the field of real-time CT navigation.

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