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FULL PAPER

Impact factors for safety, success, duration and radiation exposure in CT-guided interventions

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Objective: We aim to compare factors influencing safety, success rate and radiation dose of CT-guided biopsies and drainages in a non-teaching setting with experienced operators vs a teaching setting with residents.

Methods: A total of 1021 cases were retrospectively analyzed regarding lesion size, distance from skin, procedure duration, radiation dose, complications and clinical success. Procedures were grouped into biopsies of lung, liver, (remaining) abdomen, musculoskeletal system (MSK) and drainages of any region. Procedures in non-teaching setting were performed by experienced operators (full time interventional radiology staff), teaching setting consisted of residents under supervision of interventional radiology staff.

Results: Overall clinical success rate was 93.6 % [experienced (exp.) vs teaching setting: 93.5 and 93.6 %, $p = 0.97$]. Overall complication rate was 7.2% (5.7% minor, 1.6% major; exp. vs teaching: 8.0 and 6.5 %, $p = 0.67$).

Experienced operators performed chest and liver biopsies faster even though they were facing smaller lesions. Multiple regression analysis revealed that depth from skin significantly increased procedure duration by 36.8 s per cm ($p < 0.001$) and also radiation dose by 5.4 mGy per cm ($p < 0.001$) in all interventions. On average, teaching setting increased the duration of an intervention by 209.8 s and total radiation dose by 10.6 mGy ($p < 0.001$, $p < 0.001$ respectively).

Conclusion: CT guided interventions can be performed safe and successful disregarding anatomical parameters or teaching setting. Depth from skin and teaching setting should be taken into account both from a clinical and a time-conscious point of view since they increase radiation dose and prolong operations.

Advances in knowledge: This is the first study with >1000 interventions which shows and quantifies the impact of lesion depth and teaching setting in CT-guided interventions.

INTRODUCTION

CT-guided procedures play a valuable role in today's practice, from neck, chest and abdomen to the musculoskeletal (MSK) system, for all these locations CT-guided interventions are highly utilized.^{1–7} Both patients as well as medical professionals benefit from these techniques which reduce invasiveness compared to open surgical approaches. Studies analyzing these procedures typically place emphasis on successful histopathological or microbiological diagnosis and on complication rates, others take also factors like, e.g. lesion size or radiation doses into account.^{8–12} Since success rates are high and complication rates low, the numbers of procedures have risen over the recent years. Interventional Radiology (IR) is also part of the residency program in

most countries and new residency program requirements were approved in the USA which acknowledge IR role as an own (sub-)specialization.¹³

In the context of IR education, it is challenging to evaluate the impact of procedure specific factors as well as factors like teaching setting on both outcome and effectiveness. With this study, our first goal was to analyze success and complication rates in our cohort. We hypothesized that with proper supervision, success and complications might be similar in a teaching setting compared to a non-teaching/experienced operator setting. Secondary, we wanted to evaluate factors like duration and radiation to further analyze predictors for effectiveness of IR procedures.

METHODS AND MATERIALS

Ethics

The ethics board from the medical faculty approved this retrospective study. The need for informed consent for this study was waived by the ethics board.

Study population

From January 2011 to July 2012, 1076 consecutive interventions at the department of interventional radiology at Grosshadern University Hospital (Ludwig-Maximilians-University Munich, Campus Grosshadern, Germany) were consecutively analyzed retrospectively.

Three different types of procedures were identified: biopsies, drainages and "other interventions." All biopsies and drainages performed were included. The "other" procedures [$n = 55$ in total; pelvic screw fixation ($n = 26$), percutaneous gastrostomies ($n = 16$), thermo probes ($n = 4$), markers ($n = 4$), six diverse interventions ($n = 1$ each)] were fully excluded due to heterogeneity and small total number of each procedure. In total, we evaluated 1021 interventions in our study.

Imaging

From January 2011 to March 2012, all procedures were performed on a Siemens Somatom Definition AS+ CT scanner which was then replaced by a Siemens Somatom Definition Edge for the last few months until July 2012 (both Siemens AG, Munich, Germany). The performing radiologist operated the scanner via a sterile covered keyboard and a foot switch. Pre-, intra- and post-interventional CT images including an automatically summarization of radiation dose were all sent to the local Picture Archiving and Communication System (PACS) in DICOM format.

Preprocedural workup

Each patient was individually informed and signed an informed consent form at least 24 h prior to the intervention (excluding emergencies). The operator evaluated patient related data (patient history, medications, prior treatment, allergies) as well as coagulation status.

Interventional workflow

Breath hold and patient's position were chosen by the operator depending on body region and lesion localization. Every intervention started by running a diagnostic scan to evaluate the lesion to be examined as well as the best access path. Size and type of the biopsy needle (drainage tube, respectively) were chosen by the operator. The resident was advised by the senior supervisor.

Skin disinfection and sterile covering were applied, followed by local anesthesia (Lidocain 2%, Astra Zeneca, Wedel, Germany). The respective lesion then was targeted under visual control on an in-room dual monitor by a pedal-operated switch and the needle was shifted stepwise forwards ("Step and shoot technique"). All procedures were primarily performed with intermittent CT-fluoroscopy (10–20 mAs, 120 kV): every time the switch was pressed images of three respective slices with 5 mm slice

thickness were taken. Each operator (experienced or resident) was free to choose how often to use CT-fluoroscopy. If CT-fluoroscopy images were subjectively not diagnostic, the operator was free to perform short spiral scans of the targeted region.

In case of soft-tissue biopsies, generally two or three different specimen were taken using high-speed cutting-type needles (16G or 18G, Bard Magnum, C. R. Bard, Inc.) in a coaxial fashion; in very few cases fine needle aspiration was performed (operators decision).

For bone biopsies, a single bone core was taken using a dedicated bone-needle (12.5G or 14G SpiCut, Somatex, Teltow, Germany).

All tissue samples were sent to pathology for histological classification, in case of suspected infections additional specimen for microbiological work up were acquired. Fluid drainages were usually performed in direct trocar technique using a pig-tail drainage set (8F, 10F or 12F Flexima, Boston Scientific, Marlborough, MA, USA).

Complete retraction of the needle or definite placement of the drainage tube was defined as end of the procedure. The patient was either taken back to the ward or observed for a specific period in outpatients (2–6 h, depending on the procedure) until sent back home.

Success evaluation

All clinical and imaging reports were considered by the study coordinators (M.P, C.J.Z) to rank clinical success and to establish a standard-of-reference. If procedure results were unclear, that patient was followed up for a period of up to 1 year to validate the standard-of-reference.

Complications

In case of complications, these were categorized into minor and major.¹⁴ Minor complications were defined by vanishing of symptoms within 24 h without a specific treatment (e.g. temporary confusion, pain, small bleedings or small pneumothoraxes). Major complications were defined by the necessity for further treatment or hospitalization (e.g., placement of a thoracic drainage after pneumothorax).

Complications were evaluated during and right after the procedure by the operator. If the patient was sent back to the ward they were followed up via the electronic patient file as well as the final report written by the referring physician.

Operators and experience

A total of 13 physicians performed interventions as primary operators during the period of this study at the department. We divided the procedures into performed in a setting of experienced operators vs a teaching setting (resident supervised by staff). In the experienced setting, 485 procedures were performed by two operators who had a minimum of 5 years' experience as full time interventional radiologists (*Author 2, Author 5*). In the teaching setting, 536 procedures were performed by residents (*n*

Figure 1. (A) Biopsy of a paraaortic lymph node, depth 13.0 cm, (B) Biopsy of an intramuscular mass, depth 3.9 cm.

= 11) supervised and supported by full time staff interventional radiologists.

IMAGE ANALYSIS

Lesion size and distance from skin

Detailed analysis consisted of reviewing the DICOM images of every intervention in the Picture Archiving and Communication System PACS (Siemens AG, Munich, Germany). On axial slices, every lesion targeted was measured at the position of the intervention. The in-body-distance (Figure 1) of the needle was noted starting at the location where the skin was penetrated until the particular lesion was reached (*distance from skin*, in cm).

All lesions were by approximation considered as of elliptical shape so the largest diameter was measured as well as a relative short perpendicular diameter for calculating the area (*lesion size*, in cm^2).

Procedure duration

We defined the relevant time for the intervention as the period in which the needle was within the patient's body (*needle time*). As this was not specifically noted during the intervention, it was calculated from the first image the biopsy/drainage in which the biopsy/drainage needle penetrated the skin up until it was withdrawn as seen on the DICOM images. In case of multiple biopsies or drainages the time in between (without a needle *in situ*) was subtracted.

Radiation dose

Radiation as in cCT dose index (CTDI_{vol}) represents the output of the CT scanner. There are two ways described in literature to estimate patient's radiation exposure, "skin dose" and "effective dose."¹² Because of almost solely using intermittent mode for interventions, dose-length product, which helps with effective dose calculation cannot normally serve as a proper factor. Bauhs et al describe an estimation of skin dose.¹⁵ Because of a total dose mixture of CT-fluoroscopy as well as periprocedural (to verify the needle position), pre- and post-interventional spiral scans,

standard CTDI_{vol} was used to compare total radiation doses applied.

Statistical analysis

For statistical evaluation, we created following subgroups: all interventions, biopsies of abdominal, chest, liver or MSK and drainages of any region. The data were collected and first ordered using Microsoft Excel 2013 (Microsoft Corporation, Redmond, WA).

Statistical analyses were performed using SPSS (IBM SPSS Statistics for Windows, v. 22.0. Armonk, NY). Baseline parameters are represented as number and percentage for categorical parameters or as mean $\pm$ standard deviation for continuous variables. Student's *t*-test or Mann-Whitney *U* test were used for continuous variables to compare means, as appropriate; χ^2 test was used for discrete variables. To evaluate relationships between parameters further, we performed multiple regression analysis with either needle time or total radiation dose as dependent variable and lesion size, depth from skin and teaching setting as other variables. We included available data from procedures when data were partially missing or indeterminate. Outliers were fully included in statistical tests. For all statistical tests, a *p*-value < 0.05 was considered to be significant.

RESULTS

Of all 1021 intervention, 577 patients were male (56.5%), 444 female (43.5%). The mean patient age was 60.8 years (± 15.3 years). There was no significant difference in patient age between patients treated between experienced operators and teaching setting (age: 61.4 vs 60.5 years, *p* = .38).

485 (47.5%) were performed solely by experienced operators, 536 (52.5%) procedures were performed in a teaching setting.

Success

Overall, technical success rate was 99.9% ([exp.] vs [teach.]: *p* = 0.96; one drainage could not be placed). Clinical success rate

Table 1. Morphologic criteria lesion size and depth in between teaching settings

Means			Teaching setting			p-value	Experienced setting		
Biopsies	Abdominal	Lesion size in cm ²	24.98	±	35.75	.06	16.36	±	20.13
		Depth in cm	6.8	±	3.3	.18	7.5	±	3.2
	Chest	Lesion size in cm ²	14.12	±	24.50	.06	11.61	±	25.31
		Depth in cm	5.3	±	2.1	.17	5.8	±	2.1
	Liver	Lesion size in cm ²	19.18	±	32.46	.02	7.99	±	9.52
		Depth in cm	6.6	±	3.0	.20	7.3	±	2.8
	MSK	Lesion size in cm ²	7.77	±	13.41	.18	5.49	±	6.68
		Depth in cm	5.9	±	2.4	>.05	6.7	±	2.6
Drainages		Lesion size in cm ²	29.80	±	25.76	.21	25.94	±	28.99
		Depth in cm	5.6	±	2.6	.77	5.7	±	3.0

MSK, musculoskeletal system.

was 93.6%. Regarding both success rates, there was no significance found between experienced and teaching setting (clinical success rate: 93.5% [exp.] vs 93.6% [teach.], $p = 0.97$). There was no difference in clinical success rate for any subgroup (abdominal biopsies: $p = 1.0$, chest biopsies: $p = 0.86$, liver biopsies: $p = 0.60$, MSK biopsies $p = 0.45$, drainages: $p = 0.70$).

Complications

Complications occurred in 7.2% of all interventions ($n = 74/1021$), without finding a significant difference by setting (8.0% [exp.] vs 6.5% [teach.], $p = 0.67$). Minor complications were recorded in 5.7% ($n = 58$), major complications in 1.6% ($n = 16$). There was no death related to any intervention.

Most complications were found in chest biopsies: a total of 37 complications were recorded (26.4% of all chest biopsies, 50.0% of all complications). 8 of these 37 complications required further treatment via drainage and were therefore counted as major complication (5.7% of all chest interventions).

Looking at complications in the different settings, there was again no significant difference (abdominal biopsies: $p = 0.68$, chest biopsies: $p = 0.98$, liver biopsies: $p = 0.92$, MSK biopsies: $p = 0.09$, drainages: $p = 1.0$).

Lesion size and depth

Lesion sizes were significantly smaller for experienced operators in liver biopsies (mean: 7.99 cm² [exp.] vs 19.18 cm² [teach.], $p = .02$; Table 1). Other than that, there were no significant differences to be found. No significant difference in depth regarding settings was found in any subgroup.

Duration and radiation

In chest and liver biopsies, experienced operators took significantly less time to perform the interventions ($p < 0.01$, $p < 0.01$ respectively, Table 2).

The radiation directly associated with the intervention (CT-fluoroscopy intermittent mode) was significantly lower for experienced operators in chest biopsies and drainages ($p < 0.05$, $p <$

0.01 respectively). Furthermore, total radiation dose of drainage procedures was significantly lower if performed by an experienced radiologist ($p = 0.01$).

MULTIPLE REGRESSION ANALYSIS

Needle time

For the whole population, depth and experience had a significant impact on needle time (Table 3): per cm depth increase a procedure was prolonged by 36.8 s ($p < 0.001$). This effect was seen in the subgroups of abdominal biopsies (plus 56 s, $p < 0.001$), liver biopsies (plus 22 s, $p = 0.049$) and drainages (plus 45 s, $p = 0.008$).

Nonetheless, teaching setting prolonged a procedure (if all procedures were taken into account) by 210 s (compared to experienced setting, $p < 0.001$) which was also found in the subgroups of abdominal biopsies (plus 187 s, $p = 0.046$), chest biopsies (plus 351 s, $p < 0.001$), liver biopsies (262 s, $p < 0.001$) and drainages (222 s, $p = 0.015$).

Size of the respected lesion was neither in the whole population nor in any subgroup a significant effector on needle time.

Radiation dose

For the whole population, depth and teaching setting significantly increased radiation dose (Table 4): per cm depth, the total radiation dose increased by 5.4 mGy whereas the teaching setting added 10.6 mGy ($p < 0.001$, $p < 0.001$). In the subgroups abdominal (plus 5.3 mGy, $p < 0.001$), liver (plus 4.3 mGy, $p < 0.001$) and MSK biopsies (plus 5.6 mGy, $p < 0.001$) as well as drainages (plus 6.4 mGy, $p < 0.001$) depth increase per cm increased the respective total doses significantly. Teaching setting significantly increased the total dose of liver biopsies (plus 14.2 mGy, $p = 0.039$) and drainages (plus 10.9 mGy, $p = 0.041$) while there was also a trend in abdominal biopsies (plus 11.2 mGy, $p = 0.05$). In thoracic biopsies, no significant effect was observed. Likewise, to needle time regression analysis, size of the lesion was in no group a significantly influencing variable.

DISCUSSION

In this retrospective analysis, we analyzed over 1000 CT-guided procedures regarding safety, success rates and evaluated them

Table 2. Duration of procedures, CT-fluoroscopy and total radiation doses in between teaching settings

Means			Teaching setting			<i>p</i> value	Experienced setting		
Biopsies	Abdominal	Needle time (in min)	8.1	±	6.0	.15	6.3	±	9.6
		Fluororadiation dose (in mGy)	32.2	±	31.0	.15	25.6	±	26.7
		Total radiation dose (in mGy)	62.8	±	37.7	.36	57.0	±	40.5
	Chest	Needle time (in min)	7.5	±	5.3	<.01	3.8	±	2.8
		Fluororadiation dose (in mGy)	27.1	±	19.9	<.05	20.0	±	19.1
		Total radiation dose (in mGy)	44.3	±	47.5	.08	37.8	±	26.4
	Liver	Needle time (in min)	7.7	±	5.8	<.01	4.9	±	3.7
		Fluororadiation dose (in mGy)	33.3	±	32.6	.17	25.6	±	25.4
		Total radiation dose (in mGy)	62.6	±	42.4	.13	53.0	±	33.9
	MSK	Needle time (in min)	8.8	±	7.2	.94	8.9	±	14.2
		Fluororadiation dose (in mGy)	29.1	±	26.7	.99	29.0	±	36.6
		Total radiation dose (in mGy)	48.2	±	33.9	.72	49.1	±	41.6
Drainages		Needle time (in min)	6.5	±	6.6	.09	5.0	±	9.0
		Fluororadiation dose (in mGy)	40.7	±	52.6	<.01	26.4	±	33.2
		Total radiation dose (in mGy)	57.4	±	58	.01	46.6	±	43

MSK, musculoskeletal system.

Table 3. Multiple regression analysis of needle time by lesion size, depth increase and teaching setting

Needle time (Multiple regression analysis)		Lesion size increase (per cm ²)	Depth increase (per cm)	Teaching setting
All interventions				
Additional needle time (in seconds)		−0.8	36.8	209.8
<i>p</i> -value		.334	<.001	<.001
Biopsies	Abdominal			
	Additional needle time (in seconds)	−0.02	55.8	187
	<i>p</i> -value	.99	<.001	0.046
	Chest			
	Additional needle time (in seconds)	−0.8	16.8	351.3
	<i>p</i> -value	.673	.428	<.001
	Liver			
	Additional needle time (in seconds)	−2.7	22.1	263.9
	<i>p</i> -value	.091	.049	<.001
	MSK			
	Additional needle time (in seconds)	−1.8	35.6	44.8
	<i>p</i> -value	.751	.085	.692
Drainages				
Additional needle time (in seconds)		−0.6	44.8	222.2
<i>p</i> -value		.72	.008	.015

MSK, musculoskeletal system.

Table 4. Multiple regression analysis of total radiation dose by lesion size, depth increase and teaching setting

Radiation dose (Multiple regression analysis)		Lesion size increase (per cm ²)	Depth increase (per cm)	Teaching setting
All interventions				
Additional total radiation (in mGy)		−0.03	5.4	10.63
<i>p</i> -value		0.599	<.001	<.001
Biopsies	Abdominal			
	Additional total radiation (in mGy)	−0.11	5.28	11.23
	<i>p</i> -value	0.275	<.001	0.05
	Chest			
	Additional total radiation (in mGy)	−0.02	1.96	8.79
	<i>p</i> -value	0.877	0.205	0.188
	Liver			
	Additional total radiation (in mGy)	−0.16	4.33	14.27
	<i>p</i> -value	0.264	<.001	0.039
	MSK			
	Additional total radiation (in mGy)	0.05	5.61	4.42
	<i>p</i> -value	0.843	<.001	0.407
Drainages				
Additional total radiation (in mGy)		−0.03	6.43	10.9
<i>p</i> -value		0.775	<.001	0.041

MSK, musculoskeletal system.

further regarding influences of anatomical parameters and teaching setting on duration and radiation exposure.

Our major finding in this study was the impact of depth of a lesion, both on needle time as well as on radiation dose: 1 cm of depth increase added between 16 and 56 s to the duration of an intervention, depending on type of procedure and anatomical localization. This holds good for all subgroups but chest and MSK biopsies. In MSK biopsies, this might stem from the fact that they are mainly “superficial” lesions when compared their depths to the other biopsies (except chest biopsies but, *e.g.* breath-hold prolongs interventions) and also had the smallest standard deviation. In chest biopsies, there was also a rather small variance of depth in our cohort and also further attenuated by the fact that superficial lesions can be challenging to biopsy.¹⁶

Unexpectedly, lesion size was not a significant factor in multiple regression analysis, neither regarding duration nor radiation dose. To our knowledge, this is the first time lesion size was evaluated in relation to duration and radiation exposure in a larger cohort. During procedure planning, the operator targets a certain point of a lesion where she/he wants to hit the mark. This target point is considered to be the same irrespectively of the lesions size itself. Other studies showed that lesion size can

influence complication rates but we did not observe such an effect in this study.¹⁷

The second striking implication of our study is that teaching setting (versus experienced/non-teaching setting) substantially prolonged procedures and an increase of radiation dose was observed. In our study, we just accepted an operator as experienced if they were full-time interventional radiologists with a minimum of 5 years of experience. None of the residents had prior experience in CT-guided interventions. We believe that a stepwise approach could help to direct the right lesion to the right operator while learning IR. For example in our practice, residents start with superficial lesions in non-moving structures and only after a having some routine with those more difficult lesions should be approached. For this pathway of routing procedures, we suggest the depth apart from physiological movement should be the most important factor to make aspects like safety, quality control or structured training achievable.^{18,19}

Regarding radiation dose, a significant influence of depth was also noted: per centimeter depth increase between 4.33 and 6.43 mGy total radiation dose were added to an intervention overall. Other studies showed the positive correlation lesion depth and an increase of radiation dose in liver biopsies²⁰ but there are no

sources regarding the other regions available. We hypothesize that in MSK and abdominal biopsies, complex anatomy (relation to vessels or nerves, other organs) could be a factor. This might also hold true for drainages. In chest biopsies and drainages, amount of CT-fluoroscopy was lower for experienced operators but not for the other groups. In general, but especially in young patients dose reduction should always be considered and minimizing radiation doses is of high priority²¹ but in our cohort pre- and post-interventional scan had a larger impact on total dose than fluoroscopy radiation.

The overall success rates as well as the complication rate in our series were comparable to other studies^{4,22} and were for each body region within the reference standards by the Society of Interventional Radiology (SIR).¹⁴ The most common complications were pneumothoraces in chest biopsies, both as minor and major complications but still within the quality standards set by the Society of Interventional Radiology. The necessity of pneumothorax drainage placement did not correlate with the depth of lesions. This is consistent with Yeow et al who did not find a deeper lesion to be a risk factor to pneumothorax.¹⁷

LIMITATIONS

As this is a retrospective, single center study therefore a selection bias due to the lack of randomization is likely (as probably seen in liver biopsies due to smaller lesions for experienced operators).

Defining an operator as experienced can be quite difficult: Yeow et al regarded operators as experienced after having performed more than 30 lung biopsies, Mueller et al define an experienced operator by at least 150 (ultrasound-guided) liver biopsies while Kloeckner et al differentiate between full-time interventional radiologists and non-full-time interventional radiologists.^{17,23,24}

The difference in size of liver lesions between experienced operators and teaching setting makes comparisons difficult. Nonetheless, we included those in our study since liver biopsies tend

to be more complex and we consider this difference in size between both operator groups a real situation in IR (at least in our department).

In retrospect, it is not possible to assess when an experienced operator took over an intervention. On one hand, it is possible that this makes inexperienced operators appear faster as they would have been by themselves, but on the other hand, the operator change and the teaching environment itself adds additional time.

Evaluating clinical success can be difficult in some cases even by extending the follow-up period to 1 year. So we might have missed some diagnoses. In few cases after discussing results with the attending physicians, a rebiopsy was possible but these cases were not noted separately.

There is no record of the exact time or room time of the procedure. The time we analyzed is the *needle time* which represents the time of a needle *in situ* and potentially the most influenced part of the whole procedure.²⁵

Radiation dose was described via CTDI_{VOL} which makes it easier to compare all body regions and types of procedures. Regarding radiation dose in CT fluoroscopy, there is no exact method for effective dose measurements. As described above in the material and method section, we think that the CTDI_{VOL} approach from Leng et al is a feasible dose estimate as it describes the actual output by the scanner itself.¹² We believe that this is efficient to estimate and relatively compare the radiation exposure.

CONCLUSION

In conclusion, our results demonstrate that CT-guided procedure throughout the body can be done successful and safe in a teaching setting by residents properly supervised by staff IR radiologist. However, such a teaching setting adds more time and radiation dose.

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