#### **INTERVENTIONAL**



# Analysis of patients receiving $\geq$ 100 mSv during a computed tomography intervention

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### Abstract

**Objective** To identify a patient cohort who received  $\geq 100 \text{ mSv}$  during a single computed tomography (CT)-guided intervention and analyze clinical information.

**Materials and methods** Using the dose-tracking platform Radimetrics that collects data from all CT scanners in a single hospital, a patient-level search was performed retrospectively by setting a threshold effective dose (E) of 100 mSv for the period from January 2013 to December 2017. Patients who received  $\geq$  100 mSv in a single day during a single CT-guided intervention were then identified. Procedure types were identified, and medical records were reviewed up to January 2020 to identify patients who developed short- and/or medium-term (up to 8 years) medical consequences.

**Results** Of 8952 patients with 100 mSv+, there were 33 patients who underwent 37 CT-guided interventions each resulting in  $\geq 100$  mSv. Procedures included ablations (15), myelograms (8), drainages (7), biopsies (6), and other (1). The dose for individual procedures was 100.2 to 235.5 mSv with mean and median of 125.7 mSv and 111.8 mSv, respectively. Six patients (18 %) were less than 50 years of age. During the study period of 0.2 to 7 years, there were no deterministic or stochastic consequences identified in this study cohort.

**Conclusions** While infrequent, CT-guided interventions may result in a single procedure dose of  $\geq 100$  mSv. Awareness of the possibility of such high doses and potential for long-term deleterious effects, especially in younger patients, and consideration of alternative imaging guidance and/or further dose optimization should be strongly considered whenever feasible. **Key Points** 

• Although not so frequent, CT-guided interventions may result in a single procedure dose of  $\geq 100 \text{ mSv}$ 

• Procedures with potential for high dose includes ablations, myelograms, drainages, and biopsies

Keywords Spinal puncture · Biopsy · Radiation protection · Patient safety · Risk

#### Abbreviations

CED	Cumulative effective dose
CTDI <sub>vol</sub>	Computed tomography dose index
	(volume-weighted)
DLP	Dose length product
Е	Effective dose
ICRP	International Commission on
	Radiological Protection
IR	Interventional radiology

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# Introduction

Image-guided interventions have an increasingly valuable role in the management of patients and are expected to grow at rate of approximately 6% over the next 5 years [1-3]. Concurrent with this growth is the potential of increased radiation exposure to patients and interventional practitioners [4-7]. The main focus of radiation effects to patients has been on avoidance of tissue injuries (deterministic effects), as injuries first reported in 1993 continue to be reported, mostly with multiple procedures on the same patient [3, 6-9]. While some interventional procedures can be performed with ultrasound (US) or magnetic resonance imaging (MRI) guidance, many require computed tomography (CT), especially for interventions that require access to anatomically challenging locations and those requiring better image quality. Despite the benefits of CT

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guidance, concerns regarding inappropriate use of imaging [10], radiation risk to children [11], or potential malignancy risk [12] have been pointed out. It is often reported that the radiation dose involved in interventional procedures in terms of effective dose (E) is of the order a few mSv with only in small fraction of patients falling around 10 mSv [13–15] a dose at which stochastic effects (predominantly carcinogenic) are unlikely or uncertain.

To date, there is a paucity of information regarding patients who receive high effective dose (E) of 100 mSv or more in a single CT-guided intervention, despite there being indications in some publications that some patients may reach that level [16]. This is not to indicate that 100 mSv provides a threshold for radiation effects; however, at this level of dose, many organs may receive doses in excess of 100 mGy, a level at which radiation effects have higher certainty than at lower levels [17]. Additionally, there may be controversy on radiation effects of protracted radiation exposure occurring over a period of years but there is general agreement on stochastic effects of acute exposure at such levels of radiation dose as 100 mSv [17]. The purpose of this study is to present clinical analysis of patient cohort who received more than 100 mSv during a single CT-guided interventional procedure and dose received by the patient for each procedure. The radiation exposure of operators is not in the scope of this paper.

# Materials and methods

The Institutional Review Board waived the requirement to obtain informed consent. Data was collected using the dosetracking platform Radimetrics (Ver 2.6 Bayer HealthCare), which has data of all patients undergoing CT exams since 2013. A patient-level search was performed using a threshold cumulative effective dose (CED) of 100 mSv for the period from January 1, 2013, to December 2017. The selection criteria and further details of starting value of 100 mSv were based on recent similar studies on cumulative doses from recurrent CT scans [16]. In Radimetrics, organ doses for each exam for each patient are first calculated using reference phantoms. The effective dose is a weighted sum of all the organ doses, using organ weighting factors provided by ICRP 103 [18]. The patients who received > 100 mSv in a single day were then separated. These patients were then stratified based on procedure type. All CT-guided procedures were performed on one of three available 16-slice scanners (LightSpeed 16 and LightSpeed Xtra, GE Medical Systems) that ranged in age from 10 to 15 years. Furthermore, procedures were performed by fellowship-trained interventional radiologists with 5-25 years of experience in performing CT-guided procedures. All CT-guided procedures were obtained using helical mode, using 120 kV with two possible beam collimations (10 mm or 20 mm), three potential pitch settings (0.563, 0.938, 1.375),

fixed milliampere-seconds, and 5 mm reconstructions. Computed tomography-guided procedures involved a preliminary CT scan of the region of interest, multiple short stack CT acquisitions focused on the area of interest, and an immediate post-procedure scan at the conclusion of the procedure. The CT scanner generated DICOM dose structure reports including CTDI<sub>vol</sub>, DLP, scanning parameters of kVp, mAs, and CTDIvol for each acquisition in accordance with previous published reporting standards [19-21]. Based on the CT procedure type and dictated report, procedures were classified into 5 categories: ablation, myelography, drainage, biopsy, other. Ablation procedures were further classified as cryoablation, radiofrequency ablation, and microwave ablation. Drainages included abdominal and thoracic drainages as well as gastrostomy, jejunostomy, and thoracostomy. Biopsies included thoracic, abdominal, pelvic biopsy, and fiducial placement. As per practice existing in our hospital, referring physicians were notified within a week of procedure via correspondence of the radiation dose to their patient with recommendations for clinical follow-up to assess for skin changes. Tumor ablation and myelography patients were evaluated in the interventional radiology clinic approximately 1 month after treatment to assess for skin changes. Patients who underwent abscess drainages were evaluated either as an inpatient if they remained in the hospital beyond 2 weeks after or when they returned as an outpatient to interventional radiology for tube removal. For all patients, the electronic medical records were also reviewed to evaluate for any documentation of consultations with dermatologists for skin changes, reviewing oncology notes for possible malignancy to any organ within the radiated field, and reviewing surgical notes that reported skin graft procedures.

## Results

Radimetrics identified 8952 patients that had  $E \ge 100 \text{ mSv}$ during the period of 5 years. The details on 8952 patients have been previously reported [16, 22]. However, this study focused on patients who received 100 mSv+ in a single day and not over a period of years. There were 33 patients (M:F = 11:22) with 37 instances of CT-guided procedures each with  $E \ge 100 \text{ mSv}$  in a single procedure. Table 1 provides distribution of all procedures and corresponding doses, including the exam-level CTDIvol (scan length-weighted from multiple series) and DLP (total summation from multiple series). The scan length-weighted CTDIvol does not have rigorous scientific meanings and is only reported as a reference. The focus here is the total DLP, which is an accurate descriptor of the total incident radiation dose. The effective dose calculated by Radimetrics and via the total DLP method (with a conversion factor of 0.015 mSv/mGycm) was reported in Table 2.

Table 1 Patient demog	raphic i	information	and (	CT d	loses
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CT-guided procedure types	Number of procedures	Gender M:F	Mean age years	Exam-leve	Total DLP (mGycm)						
				Median	Mean	Range		Median	Mean	Range	
						Min	Max			Min	Max
Ablation	15	3:8	53	22.0	21.5	9.8	48.6	6113.8	6681.1	4159.6	11861.9
Myelography	8	2:6	68	28.4	32.1	11.9	71.0	6504.2	6731.1	4733.2	9450.9
Drainage	7	2:5	58	27.0	29.2	24.3	33.4	5268.5	5658.6	3876.2	7829.9
Biopsy	6	3:3	54	20.3	24.1	18.4	33.4	4111.0	4051.6	2448.5	5872.6
Other	1	1:0	90		37.1				4867.3		
Total	37	11:22	62	24.3	26.1	9.8	71.0	882.0	764.7	2448.5	11861.9

The DLP method agrees well with the Radimetrics approach, on average about 30% lower. This is mainly because that Radimetrics used patient size-matched phantoms and scan/ scanner-specific parameters, while the DLP method only assumes a single standard-sized phantom. Based on the Radimetrics data, the mean E was 125.7 (range = 100.2-235.5 mSv) and median value of all medians = 114 mSv. The largest number of cases (15) was ablations, followed by myelogram (8), drainage (7), biopsy (6), and other (1). In 4/7 (57%) drainage procedures, multiple abscesses were drained in the same procedure. The age distribution was 30-90 years. Six patients (18%) were less than 50 years of age. The mean years of follow-up was 4.2 years (range = 0.2 to 7 years). One patient was lost to follow-up. Ten patients (30.3%) died during the observation period with a mean period of 1.9 year (range 0.2 to 2.9 years) between the CT-guided intervention and time of death. All ten patients (100%) who died had preexisting conditions at the time of CT-guided interventions, including progression of malignancy (n = 6) and end-stage liver disease (n = 4). Pre-existing conditions were present in 18/23 (72%) of the remaining patients, including malignancy (n = 10) and chronic neurologic disorders (n = 8).

Three patients underwent multiple procedures on separate occasions each delivering over 100 mSv in individual procedure. One 35-year-old female with a dural tear from childbirth had 2 CT myelograms (cervical, thoracic, lumbar) with a gap of 1 month with radiation dose of 167 and 173 mSv, respectively, and cumulative effective dose (CED) = 340 mSv.

Another female patient of 68 years old had 3 CT liver microwave ablations within 29 months with effective doses of 101, 149, and 164 mSv, respectively, and CED = 414 mSv.

Finally, a 71-year-old female patient had 2 liver microwave ablations within 3  $\frac{1}{2}$  years with E of 235 and 117 mSv, respectively, and with CED = 353 mSv. No patient developed a new primary malignancy during the observation period. There were no reported skin changes in the area exposed during the CT-guided intervention.

# Discussion

The present study provides information about patients who received effective dose  $\geq 100$  mSv through a single CT-guided intervention, a finding that has important radiation risk

Table 2	Breakup of CT-guided i	nterventional procedure	s that led to effective dose $\geq$	100 mSv in a single procedure
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CT-guided procedure types		Effective dose from DLP (mSv)				Effective dose from Radimetrics (mSv)				Percentage difference in mean effective dose	
	Number of procedures	Median Mean Range		Median Mean		Range					
				Min	Max			Min	Max		
Ablation	15	91.7	100.2	62.4	177.9	121.6	137.3	100.6	235.5	- 27%	
Myelography	8	97.6	101.0	71.0	141.8	134.8	145.4	109.4	211.2	- 31%	
Drainage	7	79.0	84.9	58.1	117.4	104.3	115.3	100.4	161.8	- 26%	
Biopsy	6	61.7	60.8	36.7	88.1	109.7	116.1	100.2	142.0	-48%	
Other	1		73.0				114.0			- 36%	
Total	37	82.1	90.3	36.7	177.9	117.2	130.8	100.2	235.5	- 31%	

implications particularly for patients who are < 50 years of age and may have many years to live. Furthermore, the study includes characterization of such patients to know the type of procedures and their frequency, and the diseases associated with these patients and if there were multiple procedures on the same patient each with 100 mSv or more. Such information for CT-guided procedures has been lacking in literature and is important for the interventionalist when triaging IR procedures.

The high doses reported herein highlight the need to identify ways to ensure safety and efficacy of CT-guided interventions. The mindset that 72% of the patients are over 50 years of age and only 12% are those with non-malignant condition with longer life expectancy should not detract from the fact that these 12% cases received acute radiation exposure of > 100 mSv in a single day. The possibility of delivering over a 100 mSv in a single day during CT-guided interventions is something that has not been properly investigated and propagated. In contrast to fluoroscopically guided procedures (including CT fluoroscopy) where the physician is present in the room and actively involved in delivery of radiation, the physician is outside the scanner room while radiation is being delivered during CT-guided procedures in which helical mode is used. This increases the potential to deliver high radiation dosages, especially when the interventionist is not focused on the radiation to the patient. Two main questions arise. One: was the CT technique optimized? Second: Is there a role for replacing CT-guided procedures with ultrasound guided interventions? With regard to the first question, our center has been active in monitoring the radiation doses in patients and comparing them with reference levels. The analysis of over 9000 consecutive CT-guided interventional procedures at our institution showed that our CTDIvol per series is very similar to that of a diagnostic non-contrast abdominal CT scan, using the national bench mark from ACR (American College of Radiology) DIR (Dose Index Registry) [19]. However, there is scope for limiting the DLP. Factors such as dynamic collimation and innovations in assessing and monitoring radiation dose represent ongoing efforts to limit radiation exposure [23]. In addition, the use of CT fluoroscopy is an ongoing effort by our interventionalists to limit radiation exposure to patients undergoing CT-guided interventions. Regarding the second question, ultrasound guidance represents an obvious non-ionizing imaging alternative to CT guidance for interventional procedures. The fusion imaging was not a feature on the scanners used for the procedures reported in the current study. In fact, abdominal biopsies and ablations can be safely performed using ultrasound guidance. Ultrasound guidance, however, is less reliable for targeting tumors or collections deep in the abdomen or pelvis. Also, some tumors that are readily detected by contrast-enhanced MRI or CT are not always detected by ultrasound. This is especially relevant for patients with cirrhosis in which the liver parenchyma can be heterogeneous, making detection of a lesion challenging. For these types of cases, CT guidance is essential for safe and successful interventions. Furthermore, because ultrasound cannot penetrate bony structures, it has no role for CT myelography.

Relying on the as low as reasonably achievable principle of ICRP (18) is obviously not adequate. Risk-based principles need to be developed and propagated. While these procedures are often lifesaving, long-term implications of radiation risk should be given important place in decision-making and in research and development for newer technologies. Because this cohort of patients represents a unique opportunity to study the long-term outcomes of patients who received > 100 mSv during a single CT-guided intervention, plans are to continue to follow these patients longitudinal over several years with the goal of reporting any long-term consequences.

This study shows that the tumor ablations are associated with the highest radiation dose in CT-guided interventions (15/37, 41%). This finding is explained in part by the use of multiple helical CT acquisitions during probe placement. Several authors have shown that use of CT fluoroscopy can result in significantly decreased radiation dosages during CTguided procedures [24, 25]. Kloencker et al, found that even with the use of CT fluoroscopic techniques, radiofrequency ablation and microwave ablations were associated with high radiation doses [26]. The same authors found that 85% of total radiation doses were delivered during the preliminary planning CT and post-procedure control CT scans, which were helical scans, and suggested the preliminary imaging be restricted to regions of interest only. McCarthy et al evaluated risk factors associated with high radiation doses in 245 consecutive patients who were treated with 304 CT-guided liver ablations and found that factors such as treatment of multiple lesions on the same day, use of intravenous contrast, and large patient body habitus all contributed in increase in radiation dose [27]. Using a decision analysis Markov model, Eisenberg et al compared life expectancy losses of cohort of 30 patients with renal cell carcinoma treated with either radiofrequency ablation (RFA) or surgery [28]. The results of their study showed that while procedural-related effective dose was low (27.7 mSv), the overall cumulative dose (procedural dose plus dose associated with 1-, 3-, 6-, 9-, and 12-month followup surveillance CT) was up to 305.2 mSv versus 87.2 mSv for those who underwent surgery. It is important to note that despite the higher radiation dosages, CT-guided ablations remain a safer option particularly for older patients. The overall low risk of developing a new malignancy based on radiation exposure is counterbalanced by the existing malignancy that is being treated by ablation [25–29]. Eighty percent of the drainage procedures included in our cohort had multiple drains placed during the same CT-guided procedure. These were typically done in a sequential manner, i.e., preliminary scan, followed by CT-guided drainage followed by post-procedure

imaging were performed by each collection targeted for drainage. Fusion imaging with navigational devices which have capability of merging diagnostic CT or MRI scans with realtime US imaging during IR procedures may help to lower radiation doses in the future [28, 29].

This study has limitations. There is a paucity of information regarding potential inaccuracies in estimation of effective dose comparing products of different vendors of dose monitoring systems. The radiation doses included in this analysis only pertain to the dose received by patients through a single CTguided intervention. It did not include interventional fluoroscopy procedures and multiple diagnostic and surveillance CT scans these patients may have undergone, which can contribute significantly to the cumulative radiation dose. Also, the analysis excludes radiological examinations these patients may have undergone outside our hospital.

With increasing findings on the number of patients receiving doses exceeding 100 mSv in large part of the world, this topic requires due attention in the best interest of patient radiation safety [30].

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#### **Compliance with ethical standards**

**Guarantor** The scientific guarantor of this publication is Ronald Arellano.

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**Informed consent** Written informed consent was waived by the Institutional Review Board.

Ethical approval Institutional Review Board approval was obtained.

#### Methodology

Retrospective

Observational

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