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Setting "Typical" Diagnostic Reference Levels for most common Computed Tomography guided Interventional procedures

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ABSTRACT

Purpose: The new European Radiation Protection Law and International Radiation Protection Recommendation have stressed the need to monitor high radiation dose imaging examinations involving Computed Tomography (CT). There are no known diagnostic reference levels (DRLs) for CT-guided interventions. The scope of the study was to evaluate radiation doses and define typical DRLs.

Material and Methods: The study was conducted in a tertiary referral hospital. The most frequent consecutive CT-guided procedures performed without use of fluoroscopy within a period of 17 months included biopsies (n=31), microwave ablations of malignant liver lesions (n=12), abscess drainages (n=45) and nephrostomies (n=15). A total of 103 CT-guided interventions performed by a single interventional radiologist (>20 years of experience) were reviewed. Using the CT DICOM data, all technical and dosimetric data were retrospectively collected for analysis.

Results: There was a large variation in number of images (N) obtained and dose length product (DLP). N varied between patients depending on complexity of case. Limited dose comparison was possible due to actual absence of dosimetric data in the recent literature. Typical DLRs were established: 980, 790, 1380 and 850 mGy.cm for biopsy, drainage, ablation and nephrostomy respectively.

Conclusions: Typical DLRs were established as per the

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latest International Commission on Radiological Protection report 135 definition for CT-guided interventional procedures without use of fluoroscopy. These could serve as a basis for in-house and/or national values. As results showed that complexity of clinical case greatly affects number of slices and thus radiation dose, the authors plan to further investigate how case complexity may affect radiation dose.

KEY WORDS
CT; Interventional; Radiation dose; Monitoring

Introduction

Non-vascular Interventional Radiology (IR) services provided nowadays have led to a significantly improved patient care mostly because IR procedures are minimally invasive, resulting in fewer complications and a much shorter patient hospital stay/recovery time compared to surgery [1]. Furthermore, in specific clinical problems and despite the more recent advances in texture feature analysis derived from diagnostic imaging [2], it is only by obtaining tumour tissue, that it is possible to integrate the molecular profiling of somatic mutation into patient therapy and care.

Computed Tomography (CT)-guided interventional procedures require a core teamwork of radiologists, radiographers and medical physicists to ensure successful patient clinical outcome and safe working environment as far as radiation protection is concerned. In cases of technical complexity, procedures may involve high patient radiation doses [3, 4]. At the same time, as the number of diagnostic imaging examinations is increasing [5, 6], anxiety about radiation exposure raises [7-11]. CT is the imaging workhorse for a broad range of diagnostic and therapeutic interventional procedures because of its excellent anatomic visualisation and availability.

The only benefit for units without CT fluoroscopy is that they do not involve exposure of medical personnel; however the issue of patient exposure still remains.

The latest European Directive 2013/59/Euratom on radiation protection [12] as well as the International Basic Safety Standards (BSS) [13] provide new regulations for justification, optimisation and dose limitation for medical exposure with special focus on CT imaging. Specifically, for CT and interventional systems, the European and International BSS require that information related to radiation dose is archived within the patient examination record. Dose information should also be readily available to the radiologist during interventional procedures. Furthermore, new set of requirements for the registration and analysis of accidental and unintended medical exposures are specified, addressed for the first time in these recent regulations [12, 13].

In order to optimise radiological examinations more efficiently in terms of radiation dose, the term Diagnostic Reference Level (DRL) is used both in the European [12] and International [13] BSS. DRLs provide acceptable dose ranges for common diagnostic and interventional procedures. DLRs should be set by a professional society, regulatory authority or the Ministry of Health in each country, at a national level or by a European consortium or an International Organisation. Furthermore, the International Commission on Radiological Protection (ICRP) proposed the use of DRLs as a means of optimisation of X-ray examinations [14-16] and recently the establishment and active use of DRLs has become mandatory [17]. Regarding CT-guided interventional procedures specifically, the latest ICRP 2017 on Diagnostic Reference Levels in Medical Imaging contains a special section. As clearly stated in the particular report, "relatively few data are available on the number of procedures performed or on temporal trends, but it is clear that the numbers and types of procedures are increasing". The report also states that variability in patient dose from CT-guided interventions is dominated by procedure complexity, not patient size and that complexity factors for CT-guided procedures have not been established and there are few data from which to establish DRL values [17]. ICRP recommends that DRLs for CT-guided procedures are set in terms of Computed Tomography Dose Index (CTDI), number of sequences and CT fluoroscopy time in case of CT fluoroscopy- guided techniques. The report also defines the term "typical DRLs", as the median of the distribution of the data for a DRL quantity for a clinical imaging procedure. These DRLs may be set for a single facility to provide a com-

parator linked to a new technology or technique.

As already stated though, there are no DRL values defined either locally, nationally or internationally. There is only one study by Kloeckner et al. [18] in the recent literature that reports dose values that might serve as preliminary DRLs for commonly performed CT fluoroscopy-guided procedures.

The Cardiovascular and Interventional Radiological Society of Europe (CIRSE) continues its efforts to raise awareness on radiation protection and dose optimisation on both patients and staff [19, 20]. In view of the new European directive, CIRSE had initiated several activities [19] related to radiation protection, mainly focusing on dose monitoring and optimisation. The authors have decided to evaluate radiation doses received by patients during a variety of commonly performed CT-guided procedures. The outmost goal of the study was to define typical DRLs that could serve as a future tool towards the definition of in-house or even national DRLs for CT-guided interventional procedures that do not exist currently.

Material and Methods

The study was conducted in a tertiary referral hospital with two multi-detector CT scanners: a) a 4-slice scanner (4-Asteion, Canon Medical systems, USA) and b) a 64-slice scanner (Brilliance 64, Philips Systems, The Netherlands), the former of which is used routinely for the CT-guided interventional procedures. A wide range of CT-guided interventions are performed in an adult population, the most frequent being biopsies, radiofrequency ablations, abscess drainages and CT-guided nephrostomies.

From 1/6/2017 till 31/11/2018 a total of 103 consecutive CT-guided interventions were performed and were retrospectively reviewed. All procedures were performed by a single interventional radiologist with more than 20 years of experience. The study was performed according to the ethical standards as described by the Declaration of Helsinki.

The CT-guided procedures were conducted after clinical indications were reviewed, contraindications were excluded, and informed patient consent was obtained. Although there are few contraindications to most imaging-guided fluid aspirations and drainages, one important contraindication is the lack of patient cooperation. Relative contraindications include patients with abnormal clotting parameters: an INR of greater than 2, an elevated prothrombin time 3 seconds or more above control, or a platelet count less than 50,000/mm^3. These abnormalities can usually be corrected with appropriate blood products.

All biopsies were performed using a biopsy needle system in order to acquire appropriate tissue specimen. Nephrostomies were performed using 8 French catheters and the trocar technique. Finally, most abscess drainages were performed with the trocar technique as well; catheters used ranged from 8 to 10 French. In all cases, sterile techniques were used, and appropriate measures for gravitational effects on catheters and biopsy needle system during CT scans were taken, using sterilised gauzes in order to stabilise the catheter in proper position or the needle system biopsy, avoiding the accidental movement of patients during scanning. All patients were placed on the CT examination table in a position that facilitated the predetermined access route. Initially a planning scan was performed, with or without intravenous contrast administration to identify vascular structures, vital organs and/or areas of abnormal contrast enhancement behaviour. In general, the shortest distance between the skin and the collection or target lesion without interposing organ or vessel was chosen for needle entry and catheter insertion. Selection of the skin entry site was based on previous diagnostic studies and anatomic considerations. The preselected pathway was confirmed by immediate limited pre-procedure CT study. A wide area was sterilised and local anaesthesia was applied to the skin and underlying soft tissues where the needle and catheter would be inserted.

Trajectory planning is best accomplished by CT. Although it is best to choose the shortest pathway, it is also optimal to avoid uninvolved organs and noncontiguous peritoneal spaces. Common spaces where abscesses can form in the abdomen are the right subphrenic, left subphrenic, and lesser sac. To plan the trajectory in these areas it is crucial to understand and appreciate the spaces as they relate to the diaphragm and rib cage.

If an abscess collection for example is long, the trajectory of the puncture is planned so that the catheter lies throughout the length of the cavity when it is inserted. Two approaches may be used. First, one can choose an entrance site at the upper or lower end of the cavity so that the catheter traverses the entire length or width. The alternative is to make two punctures at the center point, one directed cephalad and one directed caudad, to permit positioning of a catheter at the top and bottom of the cavity. If an abscess is elongated in a traverse direction, catheters should be similarly placed in that transverse plane. If multiple septations are seen within a cavity, it is reasonable to

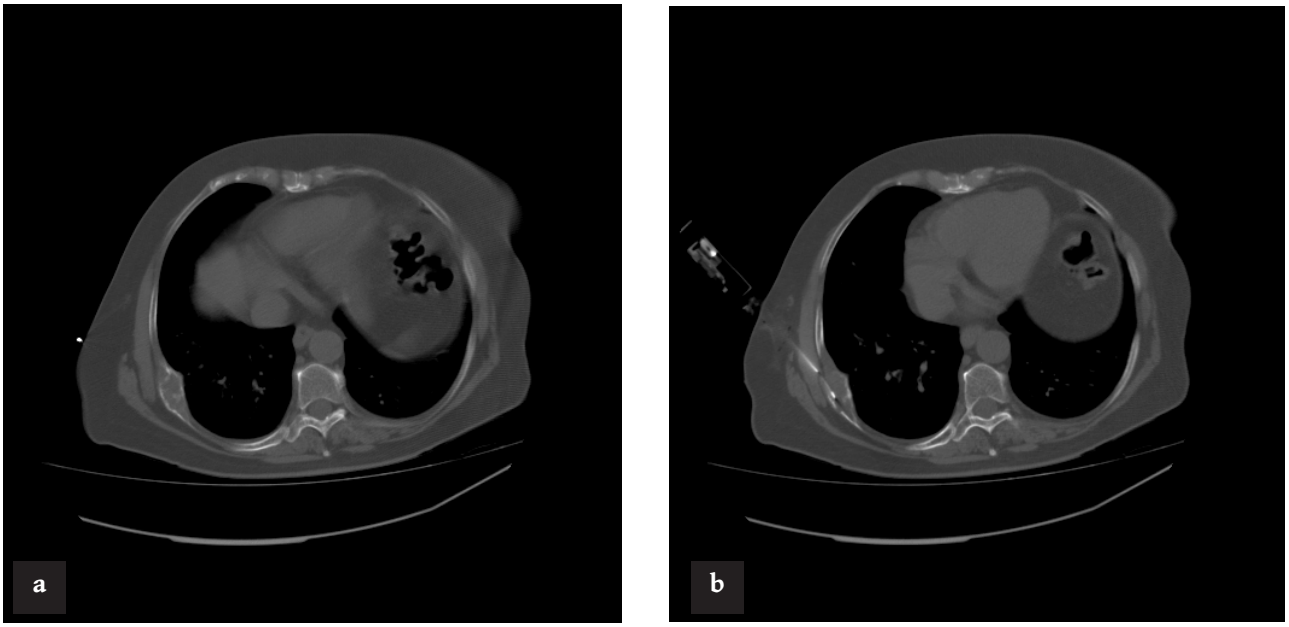

Fig. 1. a. *Axial CT scan showing a malignant appearing right lower rib lesion. The white dot on the skin represents the marker to be used for image guided core biopsy in order to verify breast cancer metastasis.* ***b.*** *Image showing cutting needle inside the lesion.*

plan the trajectory so that the maximum number of cavities would be traversed. When draining abscesses in the liver, a path that includes "cuff" of normal parenchyma to lessen the chance of tearing the thin wall of the abscess is chosen, minimising the risk of contamination along the pathway during the subsequent steps of catheter insertion. Secondly, at the time of the puncture a sufficient amount of material gets aspirated to lessen the back pressure and minimise the chance of local spillage.

The access path was assessed either on axial images or on multiplanar reformats if procedures had to be angulated to the z-direction. Preferably, the intervention was planned in a plane perpendicular to z axis. If double-angulated punctures were necessary, a tilted gantry was used for surveillance to provide images parallel to the direction of the intervention or special marking of lesion and entry point. Depending on the complexity of the procedure, several sequential series were acquired during the intervention in order to achieve a secure route path to the target lesion or abscess. Furthermore, a follow-up checkup scan was always obtained at the end of every procedure to exclude possible complications such as pneumothorax or bleeding.

As far as biopsies were concerned, positioning of the needle in the same x-y plane of an abnormality is the simplest approach if possible. In those cases, with the needle in the superficial tissues, the angle of the needle was adjusted with repetitive scans until angled correctly. When the correct angle was achieved, the device was inserted to the desired depth by using a combination of incremental adjustments, repeat scans and pre-measured distances on biopsy guns.

In the majority of cases we used the freehand approach to insert the needle into a lesion located at a different z axis position approaching the lesion as a 3D system. The final vector or angle of the needle to the lesion was a combination of two angles, the x-y angle and the y-z angle. When doing this, it is best to establish the x-y angle in the superficial tissues of the lowest slice before attempting the z angulation. When the x-y angle is proper, one can consciously hold that angle constant while moving the needle into the z axis. Patient position was adjusted depending on the target site and the specific anatomy of the trajectory. In most instances, it was simpler to have the patient lie in the prone or supine position, but other positions were also considered. In some cases, changing the patient position may "clear" the pathway for the biopsy. Before removing the patient from the table, a repeat scan was obtained to evaluate for any post procedure related complications.

The technical protocol for the CT-guided procedures was the same for all procedures (120 kVp and 130 mA). Using the CT DICOM data, all technical (kVp, collimation, table position, total mAs, pitch, etc) and dosimetric data were retrospectively collected for analysis. The only dose quantity

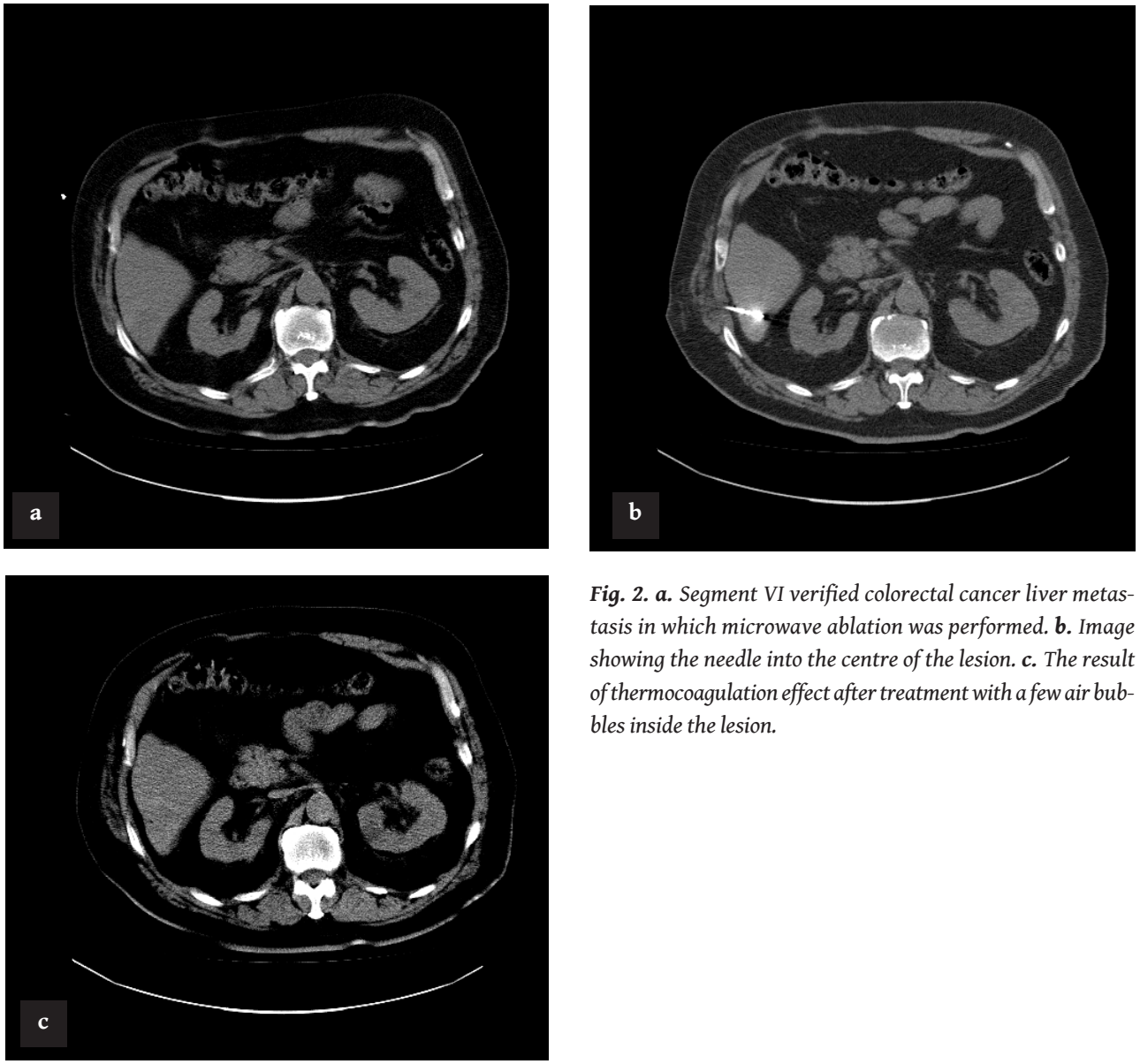

Fig. 2. a. *Segment VI verified colorectal cancer liver metastasis in which microwave ablation was performed.* ***b.*** *Image showing the needle into the centre of the lesion.* ***c.*** *The result of thermocoagulation effect after treatment with a few air bubbles inside the lesion.*

provided by the CT scanner was the Dose Length Product (DLP) measured in Gy.cm. This quantity is not actual patient dose but provides an estimate of the radiation level received by the patient during the whole CT-guided technique.

Routine CT quality control (QC) is routinely performed following a dedicated program to comply with the Greek Atomic Energy Commission (GAEC) authority requirements. The QC program includes daily, weekly, 3-month, 6-month and yearly tests by the medical physicist to ensure acceptable image quality. The Canon scanner does not provide CTDI values on the console; only DLP values. The DLP value for one rotation was verified for main routine protocols and for the interventional protocol using a calibrated solid state special chamber and measuring device (Piranha, RTI, Sweden).

Data were recorded and analysed using excel 365 (MicrosoftCorp, Redmond, USA). As some of the technical parameters, such as the number of slices (N), or DLP did not exhibit a normal distribution, data were analysed using mean value (mean), standard deviation (SD), median, min, max and third quartile (3rd quartile) for each parameter and each CT interventional technique.

Results

The study group included 31 biopsies executed mainly on liver, kidney and spine, 45 abscess drainages of liver, chest

Table 1. Patient data distribution is shown for CT guided biopsy (n=31).

	Age	*mAs*	*N*	*Collimation (mm)*	*DLP (mGycm)*
Min		2719	22	3.0	494
Max		10570	495	5.0	1756
Mean	66.5	5585	124	4.8	974
Median		**5066**	**96**	**5.0**	**975**
SD	10.4	2135	96	0.6	325
3rd Quar		6427	176	5.0	1161

N: number of slices, DLP: Dose Length Product.

Table 2. Patient data distribution is shown for CT guided drainage (n=45).

	Age	*mAs*	*Number of slices*	*Collimation (mm)*	*DLP (mGycm)*
Min		622	21	3	216
Max		13664	459	5	2839
Mean	74.1	4918	90	5	908
Median		**4208**	**41**	**5**	**793**
SD	13.7	2489	101	0.3	471
3rd Quar		5381	101	5	1053

Table 3. Patient data distribution is shown for CT guided MW liver lesion ablation (n=12).

	Age	*mAs*	*N*	*Collimation (mm)*	*DLP (mGycm)*
Min		2532	15	3.0	455
Max		13715	286	5.0	2566
Mean	66.7	7364	124	4.8	1355
Median		**6914**	**99**	**5.0**	**1377**
SD	13.2	3568	94	0.6	604
3rd Quar		9501	198	5.0	1746

(examples in **Fig. 1a** and **1b**) and kidney, 12 microwave ablations of malignant liver lesions (examples in **Fig. 2a, 2b** and **2c**), and finally 15 CT-guided nephrostomies. Patients' mean ± SD age was 71 ± 13 years. No immediate complications were observed and no patient required a repeated procedure i.e after a non-sufficient biopsy sample.

Main clinical, technical and dosimetric parameters are presented in **Table 1** (biopsy), **Table 2** (drainage), **Table 3** (ablation) and **Table 4** (nephrostomy). As the technical protocol (kV, mA) was not altered, the variation in total mAs was directly related to the total number of slices. The mean, standard deviation, median, mix, max and 3rd quartile of mAs, total number of slices (N) and total DLP in mGy.cm are provided in the Tables for the different CT techniques. There is a large variation in N and DLP in all cases. The total number of slices is varied according to case in all invasive procedures, depending on the degree of difficulty of approaching the target lesion. In certain patient cases where the number of slices is larger, this is mainly due to repeat CT scanning. This is required in order to redefine the optimum trajectory path to reach the target lesion due to changes, either to locomotor or respiratory movement that result to target position alteration. The immediate consequence of this process is increase in the number of slices and thus

Table 4. Patient data distribution is shown for CT guided nephrostomy (n=15).

	Age	*mAs*	*N*	*Collimation (mm)*	*DLP (mGycm)*
Min		1914	10	3	328
Max		11420	352	5	2260
Mean	**70.7**	**5492**	**115**	**5**	**988**
Median		4849	90	5	854
SD	10.4	2959	98	1	527
3rd Quar		6676	176	5	1224

Table 5. Comparison of median DLP with recent international literature

	Current study		*Tsalafoutas 2007*		*Kloeckner 2013**			*Yang 2018*	
CT procedure	**N**	**DLP**	**N**	**DLP**	**N**	**DLP**	**Preliminary DRLs**	**N**	**DLP**
Biopsy	31	975	14	1334	826	692	982	4425	1175
Drainage	45	793	14	840	452	648	942	2365	1125
Ablation	12	1377	14	1971	85	1403	1906	679	2351
Nephrostomy	15	854	7	710					

**CT fluoroscopy technique*

Table 6. Typical DRLs in terms of DLP for biopsy, drainage, ablation and nephrostomy

	Typical DRLs
CT procedure	**DLP**
Biopsy	980
Drainage	790
Ablation	1380
Nephrostomy	850

greater radial burden on the patient. Besides the difficulties to approach a lesion, there are several key factors that affect the total number of slices obtained and thus the radial burden of a patient such as the patients' body habitus, body mass index, location of lesion, difficulty in reaching the lesion and other complexity factors related to individual clinical case not addressed in this work, as this was a retrospective study.

Discussion

It is well known that radiation dose is influenced by many key factors of a technical, human-made or external nature. When multi-detector CT technology was introduced in clinical every day routine and especially for CT-guided interventions, there was great concern regarding high radiation effective doses but also related on its geometric efficiency. Over beaming and over scanning posed a matter of concern, particularly for CT scanning of short scan length such as CT-guided interventional biopsies that are performed at the same anatomical body region [21]. The new European legislation that is going to be adapted to the national radiation protection law and its focus on high dose CT techniques were the driving forces for this investigation.

Unfortunately, comparison with the literature was not extensive as data are extremely limited as far as CT-guided techniques without CT fluoroscopy are concerned. The only publications found using similar technology were these of Tsalafoutas et al in 2007 with limited number of patients [22], Tam et al [23] and Yang et al [24]. Tam et al performed a detailed study solely on CT-guided biopsies before and after standardisation of their image acquisition protocol. For this reason it could not be used for comparison purposes [23]. Yang et al performed a large-scale study that reported on more than 8000 CT-guided procedures [24]. **Table 5** presents the comparison made with the existing literature. Inclusion of Leng's study data was not possible, as authors provided only mean and not median values. Given the large

differences between samples, comparison using mean values was not considered accurate to be included in the table. For broad comparison purposes, Leng reported mean DLP values ranging from 902 mGy.cm (for biopsy) to 7946 mGy.cm (for cryoablation) at 16-, 40- and 64-multi detector CT-scanners [21], much higher than this study. Kloeckner et al study published dosimetric data from CT fluoroscopy interventional techniques and proposed preliminary DRLs [18]. It should be stressed that the technique using CT fluoroscopy is very different from conventional CT. DLP results from this study seem to be the lowest reported in recent literature.

The actual absence of dosimetric data in recent literature lead the authors to the decision to define typical DLRs, as per ICRP recommendation [16]. Typical DRLs were set as the rounded values of median DLP data (as shown in **Table 6**). This was done for optimisation purposes and hoping that these DRLs will serve as a basis for the regional or national values by the regulatory authority in the near future. The authors did not define typical DRLs in terms of CTDI as recommended by ICRP 135 report [16] but in DLP. The main reason for this decision was that the same technical protocol was applied in all CT-guided procedures; this would result in a similar reference DRL value for biopsy, drainage, ablation and CT guided nephrostomy respectively. The authors felt that setting one value for all techniques would not serve as the best descriptor for radiation protection optimisation purposes and preferred to define DRLs in terms of DLP. The authors could not identify any other study in recent literature that proposed any DRLs for CT-guided procedures without fluoroscopy.

Conclusion

The authors evaluated radiation doses in terms of DLP during various CT-guided procedures in view of the recent European and International legislation on safe use of ionising radiation, the increased need for radiation protection especially for high radiation dose procedures, such as CT-guided techniques, and the absence of reported regional or national DRLs for these procedures. Typical DRLs, according to the latest ICRP recommendations, were defined for CT-guided biopsy, drainage, ablation and nephrostomy (980, 790, 1380 and 850 mGy.cm) that could serve as a future tool towards the definition of regional or national DRLs that do not exist today. Radiation dose to the patient appeared to be highly dependent on a broad list of clinical factors as well such as clinical task, tumour site, procedure, complexity, patient anatomy, physician skills and experience. Thus, the authors intend to investigate the definition of various complexity indexes and their relation to radiation dose in the immediate future. **R**

Conflict of interest

The authors declared no conflicts of interest.

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