



Identification and characterization of patients being exposed to computed-tomography associated radiation-doses above 100 mSv in a real-life setting.

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ABSTRACT

Rationale and objectives: Patients receiving high cumulative effective doses (CED) from recurrent computed tomography (CT) in a real-life setting are not well identified. Evaluation of causes and patient characteristics may help to define individuals potentially at risk of radiation-induced secondary malignancies.

Materials and methods: Patients who received a CED > 100 mSv from CT scans during October 2012 and April 2020 at a tertiary university center were identified with the help of a radiological radiation dose monitoring system. The primary disease and referral diagnosis, number of CT exams, time period, age, BMI and gender distribution of the 1000 patients with the highest CED were analysed.

Results: 3431 patients had a CED of more than 100 mSv, which corresponded to 2.75% of all patients who received a CT exam. From the 1000 patients with the highest CED, mean number of CT exams per patient was 14.6, mean CED was 257 mSv (SD 98, range 177–1339). Mean age of patients was 63.9 years (SD 10.6), male to female ratio 3:2, and mean BMI 28.7 kg/m² (SD 5.5). 728 (72.9%) patients had cancer. The leading primary diagnosis was liver cirrhosis in 197 patients and 103 patients had a liver transplantation. In patients with liver cirrhosis, 750 exams were indicated for the follow-up of the disease, 662 for the clarification of an acute clinical condition, and 202 for CT-guided stereotactic radiofrequency ablation.

Conclusion: Recurrent CT scans of patients with cancer, liver cirrhosis and liver transplantation may lead to critically high CED.

1. Introduction

Computed tomography (CT) has become an indispensable diagnostic tool in cancer, transplant surgery, cardiovascular disease, polytrauma and acute medicine. Despite numerous technical advances with significant dose reductions over the last decade, exposure of patients to ionizing radiation remains a concern [1,2]. Depending on protocol and

scan range, CT exams typically produce doses of 2–20 mSv, equivalent to 1–10 years of background radiation in highly developed countries. Because of repeated acute or follow-up CT referral, an increasing proportion of patients may receive considerable high levels of cumulative effective doses (CED) [3]. Studies of occupational exposures (INWORKS) and medical exposures have found excess risks of cancer from protracted, low dose rate, exposure to ionising radiation for doses as low as

Abbreviations: BMI, body mass index; CED, cumulative effective dose; CT, computed tomography; DLP, dose length product; ED, effective dose; mSv, Millisievert; PACS, picture archiving and communications system; sRFA, stereotactic radiofrequency ablation.

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a few tens of mGy, and the risk per unit of radiation dose for cancer among radiation workers may be similar to estimates derived from studies of Japanese atomic bomb survivors [4]. For exposures of more than 100 mSv a significant risk of stochastic radiation effects including increase in cancer of the bone marrow, thyroid, bladder, breast, colon and lungs were shown, and are considered critical by the International Commission on Radiological Protection (ICRP), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), and the Biological Effects of Ionizing Radiations (BEIR) reports [5,6]. Due to the increasing use of CT in modern medicine the numbers of patients with CED > 100 mSv from CT imaging will increase and may be larger than generally expected [7]. This group of patients is still poorly studied, so a more detailed analysis with regard to primary diagnosis, age, gender, body mass index (BMI), number of CT exams and reason for CT referral was carried out at our tertiary university center.

2. Material and methods

For this retrospective study (institutional review board approval, EK-Nr: 1313/2020), a pseudonymised analysis of the picture archiving and communications system (PACS) and hospital information system database of a University based tertiary referral and transplant center was performed. An in-house radiological radiation dose monitoring system (SumDose, non-commercial) was used to retrieve digital imaging and communication in medicine (DICOM) dose reports from the PACS and to calculate the effective dose (ED) for each CT examination and CED for each patient automatically. The scan region, patient age and gender, PMMA phantom size, dose-length-product (DLP) and tube voltage were identified and extracted by the monitoring software either from the radiation dose structured report (RDSR) or obtained by analysing the secondary capture dose report with object character recognition (OCR) methods. Built-in age- and gender specific dose conversion coefficients which were based on the tissue weighting factors provided by ICRP publication 103 recommendations [8] were selected according to the scanned body regions from the Deak et al. [9] published conversion table to estimate ED by multiplying DLP with this factor. It was not considered if the entire body region or only a part of it was irradiated and if more than one region was examined during one CT series. It was assumed that each affected body part was scanned in equal parts. The conversion coefficients in [9] were specified for five body regions (head, neck, chest, abdomen, pelvis) derived by monte-carlo transport simulations using mathematical phantoms of average size adjusted for gender and 5 age categories (newborn, 1–5–10 years old and adult). The effective dose values were not corrected for actual patient body-size as this information was often not available for the monitoring software. Since an individual patient may not be at the same age and may have different weights while receiving several CT examinations, the average age and average BMI during all CT exams was calculated instead.

Patient data (age, gender) and dose data (ED, CED) including date and number of CT scans of all patients receiving a CED > 100 mSv were then exported from the radiation dose monitoring system. Since the extraction of a primary diagnosis and referral diagnosis needed to be carried out manually from the electronic medical records for each examination, we limited the evaluation to the 1000 patients who received the highest CED > 100 mSv. Diagnoses were classified according to the ICD-10 (International Statistical Classification of Diseases and Related Health Problems). Each exam was assigned to one or more codes from the ICD-10. One diagnosis was defined as the primary disease. For example, if a patient had a liver transplant due to liver cirrhosis and a CT examination was performed to rule out graft rejection, liver cirrhosis remained the primary disease. Additionally, CT studies performed for scientific reasons only were identified and excluded from further analysis. The time period until a patient has reached a CED > 100 mSv was derived from the CT study dates.

Descriptive statistical analysis of the data including frequency, distribution, mean and standard deviation was performed using IBM SPSS

Statistics 27 (International Business Machines Corporation, Armonk, NY, USA) and Excel Version 2105 (Microsoft Corporation, Redmond, WA, USA).

3. Results

124650 patients who received CT examinations from October 2012 to April 2020 were included in the basic data pool. The radiological radiation dose management system identified 3431 patients who received a CED of more than 100 mSv, which corresponded to 2.75% of all patients who received a CT exam. From the 1000 patients with the highest CED, two turned out to be inadequate labeled scientific (phantom) studies not recognized as such by the dose monitoring system. 998 patients with 14619 CT examinations remained for final analysis.

3.1. Age, gender, BMI, CED, number of CT exams

The mean age of the patients was 63.9 years (standard deviation - SD 10.6 years). 59% of patients were male. Mean BMI of the patients was 28.7 kg/m² (SD 5.5) with no relevant gender difference: men 28.9 kg/m² (SD 5.0); women 28.5 kg/m² (SD 6.1). Patients received a mean of 14.6 CT exams (SD 6.4) with a mean of 257 mSv of CED (SD 98; range 177–1339). CED were similar for men 259 mSv (SD 109) and women 253 mSv (SD 80). Patients with higher BMI had higher CED and a higher number of CT exams (See Table 1).

3.2. Time duration until CED > 100 mSv

85.7% of patients reached CED > 100 mSv within three years, and around 50% of patients reached 100 mSv or more after about 1.5 years. In only 32 patients (3.2%), the time course was longer than five years. In 17 patients (1.7%), an ED > 100 mSv was achieved with just one CT exam or with multiple CT exams on the same day. Details of the time duration are shown in Table 2.

3.3. Primary disease

The majority of patients (73%) suffered from a malignant disease, dominated by hepatocellular carcinoma and bronchogenic carcinoma. The most common non-cancer diagnoses were chronic liver diseases and vascular diseases such as aneurysms and dissections of the aorta. The proportion of malignant diseases was similar in women and men (72% vs. 73%). While this also is the case for most non-malignant diseases, typical gender-specific differences were observed. 83% of patients with acute pancreatitis were male. In addition, 86% of patients with liver cirrhosis and hepatocellular carcinoma were male, as well as the majority of patients with liver transplantation (83%). Table 3 gives a more detailed overview of the gender distribution of the most frequent diseases.

3.4. Primary disease in patients younger than 40 years

In the 22 patients younger than 40 years (2.2% of the 998 patients;

Table 1

Distribution of mean body mass index (BMI), mean number of CT exams per patient, mean cumulative effective dose (CED) and mean effective dose (ED) per CT exam per patient.

| BMI in kg/m ² | Mean number of CT exams per patient | Mean CED in mSv | Mean ED per CT exam in mSv per patient |
|--------------------------|-------------------------------------|-----------------|--|
| < 18.5 | 20.5 | 232 ± 90 | 11 |
| 18.5–25 | 17.4 | 228 ± 51 | 14 |
| 25–30 | 15.7 | 261 ± 97 | 18 |
| 30–35 | 13.3 | 277 ± 102 | 23 |
| 35–40 | 12.4 | 301 ± 174 | 28 |
| > 40 | 9.6 | 288 ± 140 | 33 |

Table 2

Time duration and corresponding number of CT exams until cumulative effective dose (CED) > 100 mSv.

| Time until CED > 100 mSv | Number of patients (%) | Mean BMI in kg/m ² | Mean CED in mSv | Mean number of CT exams |
|--------------------------|------------------------|-------------------------------|-----------------|-------------------------|
| < 7 days | 25 (2.5) | 36 ± 10 | 235 ± 51 | 6.8 |
| 7–30 day | 53 (5.3) | 30 ± 8 | 285 ± 174 | 11.1 |
| 1–12 months | 274 (27.5) | 29 ± 5 | 279 ± 99 | 13.9 |
| 1–3 years | 503 (50.4) | 28 ± 5 | 253 ± 95 | 15.7 |
| 3–5 years | 111 (11.1) | 28 ± 6 | 226 ± 60 | 15.8 |
| > 5 years | 32 (3.2) | 29 ± 5 | 217 ± 34 | 13.3 |

Table 3

Gender distribution of the most frequent primary diseases. Patients could be assigned to one or more diseases (e.g. a patient with cancer from hepatocellular carcinoma in liver cirrhosis).

| Disease | Number of females (%) | Number of males (%) | Total number |
|-------------------------------|-----------------------|---------------------|--------------|
| All cancers | 296 (41) | 432 (59) | 728 |
| Bronchogenic carcinoma | 86 (47) | 98 (53) | 184 |
| Hepatocellular carcinoma | 23 (14) | 143 (86) | 166 |
| Breast cancer | 62 (98) | 1 (2) | 63 |
| Renal cell carcinoma | 13 (27) | 36 (73) | 49 |
| Pancreatic cancer | 10 (29) | 24 (71) | 34 |
| Multiple myeloma | 9 (82) | 2 (18) | 11 |
| Liver cirrhosis | 27 (14) | 170 (86) | 197 |
| Liver transplantation | 25 (17) | 122 (83) | 147 |
| Aortic aneurysm or dissection | 49 (49) | 50 (51) | 99 |
| Acute pancreatitis | 3 (17) | 15 (83) | 18 |

11 males and 11 females), nine had cancer of which five had already metastatic disease. The remaining 13 patients had critical non-malignant disease including acute pancreatitis, Marfan syndrome and aortic aneurysm or dissection (two patients), primary thrombophilia and portal vein thrombosis, essential thrombocythaemia and Budd-Chiari-Syndrome, gastric sleeve resection with complications, gastric bypass with complications, myelomeningocele with complications, multi-visceral-transplantation, Morbus Wilson and liver transplantation (two patients), and liver transplantation (two patients).

3.5. Indications of CT in patients with liver cirrhosis

The most frequent primary non-malignant disease was liver cirrhosis (n = 197). From the total of 1819 CT exams in this group of patients, 750 exams were related to the regular follow-up of the disease. The remaining exams were assigned for an acute clinical condition or intervention. The most frequent CT referrals were suspected hepatocellular carcinoma, enrolment for liver transplantation, control before/after surgery or intervention, complications, suspected organ failure, pathologic laboratory values, and unclear focus. 229 out of 1664 CT examinations were related to CT-guided stereotactic radiofrequency ablation (sRFA) of hepatocellular carcinoma. These procedures accounted for only 13.7% of CT exams, but contributed a total of 24.4% of the CED in this population. Six patients had a CED > 100 mSv during a single sRFA procedure.

3.6. Patients with transplantation

The study population consisted of 155 patients with a transplanted organ (147 liver, 7 kidney, 1 heart, 2 haematopoietic stem cell, and 2 other tissues such as pancreas or intestine). These patients were younger and received a slightly higher CED compared with the group of patients without transplantation: 59 years (SD 9) and CED 267 mSv (SD 127)

versus 65 years (SD 11) and 255 mSv (SD 92) respectively.

4. Discussion

In the institution of the authors, 3431 patients had a CED > 100 during a 7-year period. The top 998 patients with the highest CED received a mean CED of 257 mSv (SD 98 mSv; range 177–1339 mSv) from a mean of 14.6 CT exams (SD 6.4). Mean BMI of the patients was 28.7 kg/m² (SD 5.5 kg/m²) with no relevant gender difference. Patients with CED of > 500 mSv had an average BMI of 32.8 kg/m² and received an average of 8.1 more CT exams than the study average.

62% of the patients were aged between 60 and 79 years, and 86% between 50 and 79 years. Patients with liver transplantation showed an average age of 60 years and were significantly younger than the rest of the study group. Especially young transplant patients who are under immunosuppression may be prone to cumulative radiation effects. In the study cohort, half of patients had a CED in the range of 200–300 mSv, 211 (21.1%) patients achieved more than 300 mSv, and 24 patients (2.4%) even more than 500 mSv. Furthermore, excess risks of non-cancer effects such as cardiovascular diseases may be considered [10].

Rehani et al. estimated the number of patients who may exceed a CED of 100 mSv within five years in Austria to be 15200, which would be 1.72 per 1000 inhabitants [11]. According to Frija et al. there can be considerable variation in CED between institutions, depending on the institution's medical focus and local patient conditions [12]. Our institution offers the full spectrum of oncologic treatment and transplant surgery and has the largest liver transplant unit in our state. This may have contributed to the rather high number of 2.75% of all patients receiving CED over the 100 mSv threshold compared to the range given by Frija et al. from 0% to 2.72%. These numbers may only be detected by use of a radiation dose management system, either commercial versions or by an in-house system such as applied in our institution.

From the top 998 patients with the highest CED > 100 mSv, 72.9% patients had cancer, with the majority having hepatocellular (n = 166), lung (n = 184), colorectal (n = 71) and breast cancer (n = 63). 197 patients had liver cirrhosis and 103 patients had liver transplantation. A malignant primary disease was similar among females and males; however, 86% of patients with liver cirrhosis, and 86% of patients with hepatocellular carcinoma were male. In patients with liver cirrhosis, the most frequent indication for CT was follow-up (n = 750), followed by acute referrals (n = 662). Patients with liver cirrhosis most frequently receive multiphase CT exams including native, arterial, portal, and delayed phase, contributing to rather high cumulative doses from a single examination. Furthermore, acute evaluation of post-transplant hepatic perfusion as well as evaluation in acute bleeding may require multiphase imaging including two to three CT phases.

From 1664 CT exams in patients with hepatocellular carcinoma, 229 exams were related to CT-guided sRFA [13–15]. sRFA demonstrated high technique effectiveness, safety, and inter-operator performance, even for treatment of large volume disease, subcapsular, subphrenic and multiple lesions [16]. There is currently no information about the radiation exposure of patients receiving sRFA. The procedure requires planning CT scans in arterial and portal venous phase, non-enhanced control CT(s) for verification of needle position, and final arterial and portal venous phase control CT scans for verification of the complete ablation necrosis and rule out of bleeding complications. In addition to the CT scans needed for surveillance and staging of liver cirrhosis and HCC, CT-guided sRFA means quite a large number of additional CT scans and therefore was included for analysis. The CT exams during sRFA accounted for 13.7% of CT exams but contributed a total of 24.4% of the effective dose in this population. According to Arello and co-worker, CT-guided ablations may eventually result in effective doses of more than 100 mSv from a single intervention [17]. Factors such as treatment of multiple lesions on the same day, use of intravenous contrast, and large patient body habitus may all contribute to an increase in radiation dose [18]. In our cohort six patients had CED > 100 mSv during a single

sRFA procedure.

In patients under the age of 40 without an underlying malignant disease, the majority had rare, congenital, or acquired severe chronic diseases. Two of the 13 patients suffered from Marfan syndrome and two patients suffered from Wilson's disease, which required liver transplantation. In Rehani et al. half of CT exams in patients less than 40 years of age with non-malignant diseases who received CED > 100 mSv were unrelated to follow-up of a primary chronic disease but were referred for unclear acute indications [19]. Remarkably, retrospective evaluation of appropriateness showed that for all CT exams combined, 2% showed low utility, 38% were marginal, 27% were indicated, and 33% were unscanned. In Brambilla et al., 6.1% of all patients who underwent CT exams in a 2.4-year period received a CED > 100 mSv, of which 1.5% received a CED > 100 mSv in a single episode of care within 1 month after the first CT exam [20]. Most of these patients had non-oncologic indications for CT referral. The median number of CT exams needed to overpass 100 mSv was in the range of 1–4, and the median number of acquisitions was in the range of 6–11, which confirmed the high relevance of multiphase examinations as a cause of increased CED.

Use of a dose management system is helpful for survey of CED. Application of appropriateness criteria through clinical decision-support and optimized protocols by keeping doses below the national benchmark doses is strongly recommended to reduce unnecessary radiation exposure [21]. Customising protocols may become more and more important. In patients with liver cirrhosis, surveillance using a low dose thoracic CT exam and liver magnetic resonance imaging instead of multiphase abdomen CT is recommended. In oncology patients, a dose reduced thoracic and abdomen CT may be diagnostic for restaging and follow-up. Scientific evidence for imaging referral and frequency of CT intervals during surveillance is crucial [21]. Furthermore, regular updates in diagnostic reference levels for CT are needed to address continuous improvement of CT dose saving technology [22].

4.1. Limitations

The study has several limitations. Quantifying radiation burden depends on risk surrogates and may only give a rough estimate [23]. The calculated effective doses represent dose estimates for an “average patient”. Height reference values were 163 cm for women and 176 cm for men, weight reference values were 63 kg for women and 73 kg for men. Therefore, large overweight patients actually get less effective dose than calculated, while a small underweight patient actually gets more effective dose. Furthermore, the organs of young patients react significantly more sensitively to ionizing radiation than those of old patients, which is not considered by using the same tissue weighting factors [24]. For patients in their 60 s, the lifetime risks are estimated to be about half those for patients in their 30 s, falling to less than one-third for patients in their 70 s and about one-tenth for those in their 80 s [25]. Only cumulative effective doses from CT scans were included. Certainly, patients with aortic aneurysms, undergoing EVAR (endovascular aortic repair), and in particular patients with complex FEVAR (fenestrated endovascular aortic repair) procedures will have additional relevant exposures to ionizing radiation. This also refers to patients with liver cirrhosis undergoing TIPS (transjugular intrahepatic porto-systemic stent shunt), or patients with HCC who may also have one or multiple exposures during chemoembolization. Inclusion of CT scans from the department of radio-oncology was beyond the scope of our study, and these scans are stored in a different PACS system not accessible to us. We did not analyse the effect of new CT scanners and protocol changes on CED. In our real-life evaluation, the underlying diseases and image referral were manually obtained from available data from the electronic health records, which were sometimes imprecise and incomplete. Patients frequently have more than one diagnosis and the imaging referral can be related to different medical problems. The appropriateness of the imaging referral and medical value of imaging were not evaluated. Only the top 998 of patients with the highest CED > 100 were analysed,

however this group of patients is the one who carries the most critical risks from ionizing radiation. The true rate of radiation-induced secondary malignancies remains unknown.

Ethical statement

This retrospective study was approved by the institutional review board of the Medical University of Innsbruck, EK-Nr: 1313/2020 and was conducted in accordance with the Helsinki Declaration as revised in 2013. The COPE guidelines were followed.

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CRediT authorship contribution statement

Gerlig Widmann: Conceptualization, Methodology, Project administration, Resources, Software, Supervision, Validation, Roles/Writing – original draft, Writing – review & editing. **Andreas Beyer:** Data curation, Formal analysis, Investigation, Methodology, Project administration, Visualization, Roles/Writing – original draft, Writing – review & editing. **Werner Jaschke:** Conceptualization, Data curation, Formal analysis, Project administration, Resources, Software, Supervision, Validation, Writing – review & editing. **Anna Luger:** Formal analysis, Validation, Visualization. **Heinz Zoller:** Conceptualization, Data curation, Investigation, Methodology. **Herbert Tilg:** Conceptualization, Methodology, Resources, Supervision, Validation. **Stefan Schneeberger:** Conceptualization, Methodology, Resources, Supervision, Validation. **Dominik Wolf:** Conceptualization, Methodology, Resources, Supervision, Validation, Writing – review & editing. **Elke R. Gizewski:** Conceptualization, Methodology, Project administration, Resources, Software, Supervision, Validation, Writing – review & editing. **Robert Eder:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Writing – review & editing. **Pavle Torbica:** Conceptualization, Data curation, Formal analysis, Software. **Michael Verius:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Roles/Writing – original draft, Writing – review & editing. Gerlig Widmann and Andreas Beyer contributed equally to this paper.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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