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# Increasing use of computed tomography scans in the North Denmark Region raises patient safety concern

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Published in:

European Journal of Radiology

DOI (link to publication from Publisher): 10.1016/j.ejrad.2023.110997

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Publication date: 2023

Document Version Publisher's PDF, also known as Version of record

Link to publication from Aalborg University

Citation for published version (APA):

Westmark, S., Hessellund, T., Hoffmann, A., Madsen, B. B., Jensen, T. S., Gielen, M., Bøggild, H., & Leutscher, P. D. C. (2023). Increasing use of computed tomography scans in the North Denmark Region raises patient safety concern. European Journal of Radiology, 166, Article 110997. https://doi.org/10.1016/j.ejrad.2023.110997

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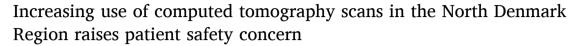
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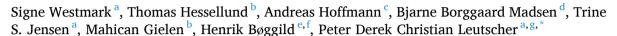
# European Journal of Radiology

journal homepage: www.elsevier.com/locate/ejrad



# Research article





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# ARTICLE INFO

# Keywords: Computed tomography scan Clinical indication Ionization radiation

# ABSTRACT

*Purpose*: Use of computed tomography (CT) scans raises safety concern as lifetime cumulative ionising radiation exposure is associated with risk of developing malignancies. This study aimed to investigate use of abdominal CT scans in the Danish health care sector.

Methods: Data on abdominal CT scans performed annually in the North Denmark Region between 2005 and 2018 were extracted from the regional registry with emphasis on patients with a medical history of a repeated abdominal CT scan within 28 days. An audit of the medical files was subsequently conducted in 100 randomly selected patient cases to evaluate clinical information being provided, in addition to justification for a repeated abdominal CT scan, and finally if other radiology modalities could have been applied.

*Results:* Number of annually performed abdominal CT scans in this demographically stable regional population increased by a factor 4.3 from 15 in 2005 to 65 in 2018 per 1,000 inhabitants. The audit revealed that 31% of the second abdominal CT scans within a 28 days period were categorized as either *doubtful whether justified* or *not justified*. Moreover, 20% of the CT scans were considered replaceable by ultrasonography.

Conclusions: Annual performance of abdominal CT scans increased fourfold during the 14 years period. This tendency is probably attributable to changes in the Danish health care sector by which CT scan examination are used more frequently aiming at more accelerated patient investigation flow in conjunction with shorter length of hospitalization stay. Alertness is strongly warranted towards the associated risk of cancer due to life-time cumulative ionising radiation exposure by this strategy.

# 1. Introduction

Along with the advancements in medical technology, the number of computed tomography (CT) scans performed in the health care sector has been increasing in the last few decades, enabling fast and accurate diagnosis with a description of underlying pathology [1–3]. However, the benefit of a diagnostic procedure must always be evaluated against any potential harm this procedure may cause. The rationale applies in particular to CT scans. From a patient safety perspective, the CT scans contribute to a concerning source of ionising radiation. CT scanning is an imaging technique using high doses of ionizing radiation, 100–500 times

the radiation from conventional radiography [2]. In 2003, CT scans accounted for approximately 15% of all ionizing imaging procedures, whereas CT scans accounted for 70% of the total ionozing radiation dose exposure to patients in conjunction with these procedures [4].

Brenner and Hall [2] have estimated that approximately 1.5–2% of all cancers in the United States in 2005 were associated to ionizing radiation exposure from CT. Along with other research groups they advocate for a higher level of clinical justification of CT scans. It is suggested that approximately one-third of all CT scans can be avoided, and to some extent be replaced by other radiology modalities, including ultrasonography or magnetic resonance imaging [1,2,5–9].

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The conduction of a national audit survey on the clinical justification of CT examinations in Sweden in 2009 revealed that 20% of the examinations were considered as unjustified [10]. In that context, justified CT scans are defined as scans where the benefits of the scan exceed the risks of the scan itself [11]. Thus, unjustified CT scans are the scans with higher risks than benefits, and this category of CT scans should therefore be targeted as avoidable scans.

Moreover, it has also been suggested to diminish ionizing radiation dosing in the CT scan procedure aiming to reduce the life-time risk of associated cancer development [1,2,5-9]. High doses of ironizing radiation are used in CT scans of the abdomen and the pelvic region, which affect the more radiation-sensitive organs, like the digestive organs or the red bone marrow, leading to an increased risk of leukaemia, myelodysplasia and solid tumours [1,9,11-13]. Thus, reduction of ionizing radiation exposure to the abdomen, either by avoiding unjustified CT scans and/or to diminish dosing would be an essential strategy to prevent CT scan-induced cancer [1,5,13].

This study aimed to assess changes in number of annual abdominal CT scans performed in the North Denmark Region and to evaluate distribution of different clinical justification levels for performance of abdominal CT scans.

# 2. Methods

Data on performed abdominal CT scans in the North Denmark Region from January 1st 2005 to December 31st 2018 were extracted by the regional administrative Business Intelligence (BI) office. The region encompasses two main hospital entities divided into six separate departments providing radiological services to approximately 590,000 regional inhabitants by 2018.

In the study particular emphasis was made on performance of abdominal CT scans by which an index abdominal CT scan followed by a repeated abdominal CT scan performed on the same patient. Data on repeated abdominal CT scans performed in two 13-months periods from January 1st 2008 to February 1st 2009 and January 1st 2017 to February 1st 2018, respectively, were analysed. To allow the participants, who had been examined with an abdominal CT scan in December to have a repeated CT scan included in the analysis, we expanded the index year from January to December to also cover January in the following year, thus constituting a total of 13 months for each period. The first for the two 13-months periods included in the analysis was originally intended to be 2005. However, complete data necessary for the analysis was accessible only from 2008 due to implementation of new health data system in the North Denmark Region during 2007 and therefore 2008, and not 2005, was selected to represent the earliest possible year in the overall observation period for comparison with

All patients having at least two abdominal CT-scan in the 28-day period were identified and consecutive abdominal scans were recorded. Because any repeated CT scan, independent of the time frame between scans, contributes to the cumulative ionising radiation exposure of the patient the total number of CT scans were summarized. For the study purpose, an interval of 28 days was selected to assess the prevalence of repeated scans in a uniformly and most clinically relevant manner. A preliminary analysis of the repeated CT scans being performed within a 14-day interval revealed that this interval was too short and that there was a clear pattern of second CT scans being performed in the following two weeks after the initial 14 days interval. Moreover, second CT scans after day 28 and until day 56 day were by far less commonly observed. Hence, it was decided to apply the 28 days interval in the study. In addition, there was also concern about inclusion of second CT scans beyond day 28 day, because an extended time-period could increase the likelihood of new clinical events to occur not necessarily related to the primary clinical event linked to performance of the first CT scan.

The CT scan code system is a Danish version of the International

Classification of Diseases and Related Health Problems (ICD-10). In Denmark, the ICD-10 system is incorporated into the Health Classification System (SKS), which in addition to the classification of diseases also classifies the different radiology services, including topographies and operation procedures. Each abdominal scan was defined as a regional code package with an accession number. The package included other codes holding information on the patient unique personal identification number, date of the CT scan, use of intravenous contrast medium, and cancer assessment information related to cancer screening and follow-up. From the personal identification number sex and age of the patient were identified. Age was recoded into age groups.

# 2.1. Medical file audit

The audit aimed to assess the sufficiency of clinical referral information and justification of abdominal CT scans being repeated within 28 days of a previous abdominal CT scan in the same patient. A subgroup of 100 patients from a 2017/2018 index study population with a second abdominal CT scan performed within 28 days after a previous abdominal CT scan was randomly selected to be part of the clinical audit. The audit was performed in a blinded manner by two radiologists: A and B, respectively. Radiologist A is affiliated to another Danish region than the North Denmark Region and radiologist B to the North Denmark Region. The two radiologists had access to the abdominal CT scan referral document and the descriptive radiology report for each of the 100 patient cases in the audit, but not to the abdominal CT scan images. The cases were audited by the two radiologists separately and afterwards the audit evaluations between the two radiologists were compared and discussed aiming for final consensus in the evaluation.

By use of four-grade scales [10], the two radiologists rated the quality of information provided by the clinician in the referral to a second abdominal CT scan as either 1) adequate, 2) relatively adequate, 3) not really adequate, or 4) inadequate. Likewise, the auditor also rated the clinical justification for performance of a second abdominal CT scan as either 1) justified, 2) most likely justified, 3) doubtfully whether justified, or 4) not justified. Hence, a second abdominal CT scan was determined not justified if there was major inconsistency and/or lack of relevant clinical information of the referral for the second CT scan or if the request of the second referral was answered by the first CT scan, or if no significant clinical event, including new signs, symptoms, laboratory results and other findings, had occurred in the period between the first and second abdominal CT scan. Likewise, a second abdominal CT scan was determined *justified* if there was no inconsistency and/or no lack of relevant clinical information of the referral for the second CT scan or if the request of the second referral was not answered by the first CT scan, or if any significant clinical event had occurred in the period between the first and second abdominal CT scan. The two intermediary grades (most likely justified and doubtfully whether justified) were considered optional rating alternatives for the auditing radiologists if the criteria for the two other strict grades were not met completely. Moreover, the auditors also evaluated if a abdominal CT scan could have been replaced by an ultrasonography examination or a magnetic resonance imaging (MRI). The purpose of this part of the audit was to evaluate if there were other applicable radiology modalities without use of ionising radiation and still providing the image-based information as needed for the clinical investigation of the patient.

# 2.2. Ethical approval.

This clinical quality assurance study was approved by the hospital management. The study did not require ethical approval and it was registered at the research project office in the North Denmark Region.

# 2.3. Data presentation and statistical analyses

The number of scans per year is reported as proportions of the

population in the same year (Statistics Denmark) with estimated confidence intervals. For the two 13-month periods (2008 and 2017, respectively) the number of reported abdominal CT scans, regardless of the time between them in the period, were summarized. All ratio-interval scales were heavily screwed and were described using 1., 2. (median), and 3. Quartile. Data handling and analyses were conducted in Stata v. 16.1 (STATA Corporation, College Station, USA).

# 3. Results

The number of abdominal CT scans in the North Denmark Region increased from 8,930 in 2005 to 38,305 in 2018. Hence, the number of abdominal CT scans per 1,000 inhabitants increased by a factor of 4.3 from 15 in 2005 to 65 in 2018 (Fig. 1), whereas the proportion of abdominal CT scans in comparison to all CT scans increased from 39% to 58%, respectively (Fig. 2). In the same period, the number of inhabitants in the region increased by 2% from 577.278 to 589.148, whereas the percentage of inhabitants in the region above 60 years of age increased from 22% in 2005 to 27% in 2018 [14].

In the first study period from January 1st 2008 to February 1st, 2009, 914 different patients (53% males) with an median age of 63 years (IQR 53-72) underwent abdominal CT scan examinations in two or more separate occassions (n = 2,369 examinations). Among the 914 patients, 432 (47%) had a second abdominal CT scan undertaken within 28 days after a previous abdominal CT scan. In the second study period from January 1st 2017 to February 1st 2018, the number of patients increased by a factor 2.6 to 2,415 patients (50% males) with a median age of 69 years (IQR 59-76), whereas the number of abdominal CT scan examinations increased by a factor of 2.8 (n = 6,646). Among the 2,415 patients the number of patients undergoing 4 or more CT scan examinations increased by a factor of 3.9 from 54 (range 4 to 12 scans) in first study period to 213 (range 4 to 20 scans) in the second study period. In total, 432 (48%) CT scan pairs were performed within the 28 days interval in the first study period versus 1,138 (48%) in the second study period.

# 3.1. Medical file audit

Table 1 presents demographic characteristics and the finally

consented outcomes of the medical file audit by the two radiologists. Median age of the audited patient population (n = 100) was 67 years (IQR: 53–75) and 49% were males. Abdominal abscess (n = 34) was the most common reason for performance of a repeated CT scan within 28 days, followed by ileus (n = 18), sepsis/infection (n = 10), and perforation (n = 7). Other (n = 31) accounted for the category of nonspecified reasons or more than one reson being stated. The provided clinical information in conjunction with referral to a second CT scan was rated either as not really adequate or inadequate in 30% of the patient cases. Likewise, 31% of the repeated CT scans were rated as either doubtful whether justified or not justified. Furthermore, 23% of the repeated CT scans were considered replaceable by either ultrasonography or MRI. The figure was 44% in the abscess subgroup.

#### 4. Discussion

In the present study, we have shown that the number of abdominal CT scans performed has increased by a factor of 4.3 per 1,000 inhabitants in the North Denmark Region in period of 14 years from 2005 to 2018. In the same period, the number of CT scanners in Denmark increased from 70 to 230, hence a three-fold increase [14]. Today, more than one million CT scans are performed annually in Denmark with a population of 6 million people. Although the percentage of elderly persons above 65 years during this period increased from 22% to 27% in the general population, this increasing age cannot itself explain the significant increase in CT scan activity. Hence, other factors must also contribute to this phenomenon, including existing CT scan referral practice, which could be explained by the demand in recent years for more rapidly clinical investigation to reduce length of hospitalisations and attributable expenses as part of an overall cost-saving and efficieacyincreasing strategy in the Danish health care sector in the last twenty vears.

Other factors may also have contributed to the significant increase in CT scans in Denmark. In 2008 a new cancer patient pathway program was implemented in Denmark with the main objective to improve on different parameters related to control of cancer, including more timely diagnosis and earlier detection of cancer among incident cancer patients in primary care. In support of the program additional CT scanners were therefore provided to the Danish Hospitals in the following decade,

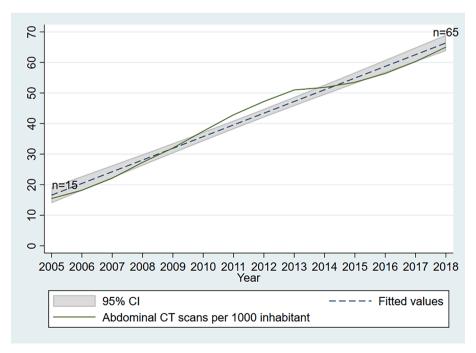


Fig. 1. Numbers of performed abdominal CT scans per 1000 inhabitant from 2005 to 2018 in the North Denmark Region.

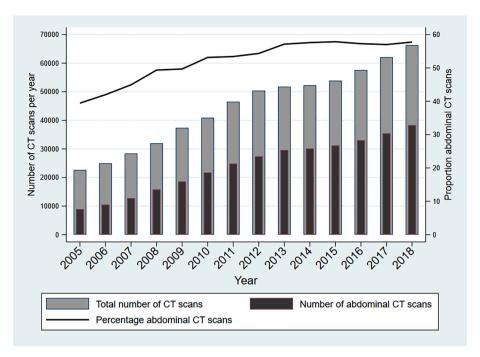


Fig. 2. Numbers of abdominal CT scans in comparison to all CT scans from 2005 to 2018 in the North Denmark Region.

Table 1

Demographic characteristics and outcomes of the medical file audit in accordance to indication of the repeated abdominal CT scans within 28 days.

	Total	Absces	Ileus	Sepsis/Infection	Perforation	Other <sup>1</sup>
	N = 100	n = 34	n = 18	n = 10	n = 7	n = 31
Gender, n (%)						
Male	49	17 (50)	5 (28)	4 (40)	4 (57)	19 (61)
Female	51	17 (50)	13 (72)	6 (60)	3 (43)	12 (39)
Median age, years (IQR)	67 (53–75)	61 (46-70)	72 (54–79)	70 (65–71)	59 (49-71)	72 (62–78)
Level of clinical information, n (%)						
Adequate	51	21 (61)	10 (56)	3 (30)	3 (43)	14 (46)
Relatively adequate	19	7 (21)	5 (28)	1 (10)	0	6 (19)
Not really adequate	16	2 (6)	3 (16)	2 (20)	3 (43)	6 (19)
Inadequate	14	4 (12)	0	4 (40)	1 (14)	5 (16)
Level of clinical justification, n (%)						
Justified	55	22 (64)	12 (66)	3 (30)	5 (70)	13 (41)
Most likely justified	14	4 (12)	3 (17)	3 (30)	1 (15)	3 (10)
Doubtful whether justified	14	5 (15)	2 (11)	0	0	7 (23)
Not justified	17	3 (19)	1 (6)	4 (40)	1 (15)	8 (26)
Alternative modality to CT-scan, n (%)						
Ultrasonography (US)	20	15 (44)	1 (11)	1 (10)	1 (14)	2 (6)
Magnetic resonance imaging (MRI)	3	0	0	0	0	3 (10)
US and/or MRI (net total)	23	15 (44)	1 (6)	1 (10)	1 (14)	5(16)

Malignancy suspected (n = 6); hernia (n = 3), adrenal gland tumor (n = 2), liver tumor (n = 2), post-operative complications (n = 2), status after liver. resection (n = 1), edema (n = 1), lymph node status (n = 1), trauma (n = 1), abdominal thrombosis (n = 1), gall-bladder lesion (n = 1), palpable abdominal. filling (n = 1), cholangitis (n = 1), and non-specified reason or more than one reason stated (n = 8).

which can also explain the three-fold increase of CT scanners along with the increase of similar increase in CT scans. Furthermore, a tendency towards a more defensive diagnostic approach seems more common in the Danish health care system, which is probably related to a similar tendency among patients and relatives in Demark more frequently filing medical complaints against hospitals. An element of such complaints could have been an unmet expectation of a complete examination program, including a CT scan, which is often considered highest standard of health assessment by many patients.

The medical file audit in the study demonstrated an *not justified* CT scan proportion of 22% among repeated abdominal CT scans within 28 days after a previous abdominal CT scan. This estimate has been reported in studies from other countries, estimating the proportion to be 20-39% of all CT scans [10,15-17]. Repeated CT scans lead to cumulative ionizing radiation exposure, which is associated with an increased

risk of radiation-induced cancer development. The effective dose from a diagnostic abdominal CT scan is normally estimated to be approximately ten millisieverts (mSv) of radiation [2]. Such a dose quantity has been associated with a risk of approximately 1 in 1,000 developing cancer. However, it is difficult to estimate the lifetime attributable risk of cancer, based on single CT scan radiation exposure. The risk rather depends on the cumulative effective dose exposure [18].

In the medical file audit it was evaluated that nearly one-third of the abdominal CT scans could have been replaced by ultrasonography. Because of high diagnostic sensitivity in comparison to the CT scan, the ultrasonography may replace the CT scan as a diagnostic tool in patients with cholecystitis and pancreatitis, and possibly also patients with appendicitis and diverticulitis [16]. This optional use of the ultrasonography is important to have in mind, because the ultrasonography does not expose the patients for ionising radiation, and is, therefore, not

associated with the risk of cancer development. However, the performance and sensitivity of ultrasonography are highly user-dependent, and the examination should be performed by an experienced user [19]. Laméris et al. [20] found that ultrasonography followed by CT scan if ultrasonography was inconclusive, was the most sensitive method in the assessment of patients with acute abdominal pain in the emergency department. Furthermore, this approach led to lower overall radiation exposure, because only half of the patients needed a CT scan after an ultrasonography. The expected outcome of this strategy would be the reduction of waiting time in the radiology department, and also in costs and cumulated radiation exposure.

This study has some limitations. Only repeated scans were investigated in the audit, as the first scan performed in each pair of scans was assumed to be justified. Thus, possible not justified first scans were not investigated and our estimate must be regarded as conservative. Hill et al. [8] showed that CT scans often are repeated because of transfers to other hospitals. In this study, we only investigated repeated CT scans performed in the North Denmark Region, including the two main hospitals in the region. If a patient had a CT scan performed in another region of Denmark, this scan was not included in this study, and thus, the number of repeated not justified scans may have been underestimated. Hill et al. [8] also showed that incompatibility between software used in the different institutions was a common reason for repeated CT scans without clinical justification.

The same problem has also been encountered in Denmark. The country is divided into five regions, including the North Denmark Region, with independent health care administration and management in each region. The clinical guideline and procedures within the different specialities, such as radiology, are not necessarily identical between the different regions. Even within the same region, CT scan protocols might differ from one hospital radiology department to another. In that context, the development of standardised procedures and the use of a uniform IT booking and file system across different clinical and administrative health care entities have been identified as potential means to reduce not justified CT scans. In that context, it is important to provide education and training to clinicians to be alert about cautious use of CT scans whenever possible. Keijzers and Britton [21] have shown that the physicians in the emergency department, in general, have poor knowledge about the risks of cancer development associated with CT scan-induced radiation.

# 5. Conclusions

The findings in this study raise safety concerns regarding the increase in abdominal CT scans, and the associated risk of cancer development. What has been observed in this region in Denmark may occur as well in other countries in Europe. Clinical education and quality assessment are needed as important measures to reduce performance of *not justified* CT scans. Use of ultrasonography or magnetic resonance imaging to replace CT scans when possible, the development of clinical decision support systems, and more compatibility in software programs are other tools that should be applied to control *not justified* CT scans.

# CRediT authorship contribution statement

Signe Westmark: Writing – review & editing, Writing – original draft, Validation, Formal analysis. Thomas Hessellund: Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Data curation, Conceptualization. Andreas Hoffmann: Writing – original draft, Investigation, Formal analysis, Data curation. Bjarne Borggaard Madsen: Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. Trine S. Jensen: Writing – original draft, Methodology, Investigation, Formal analysis, Data curation. Mahican Gielen: Investigation, Writing – review & editing. Henrik Bøggild: Writing – original draft, Visualization, Validation, Supervision,

Software, Resources, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Peter Derek Christian Leutscher:** Writing – review & editing, Writing – original draft, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization.

# **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.

# Data availability

The datasets generated and/or analysed during the current study are available from the corresponding author.

# Acknowledgements

We thank Andreas Egmose, Business Intelligence office, North Denmark Region, and Maria Roer,

North Denmark Regional Hospital, for kind assistance regarding the data collection.

# Funding

This research did not receive any applicable funding.

# Ethical approval

This clinical quality assurance study was approved by the hospital management. The study did not require ethical approval and it was registered at the research project office in the North Denmark Region.

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