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Cumulative exposure to ionising radiation from diagnostic imaging tests: a 12-year follow-up population-based analysis in Spain

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ABSTRACT

Objectives To calculate each patient's cumulative radiation exposure and the recurrent tests during a 12-year study period, according to sex and age, in routine practice.

Design Retrospective cohort study.

Setting A general hospital with a catchment population of 224 751 people, in the Southeast of Spain.

Participants Population belonged to the catchment area of that hospital in 2007. We collected all consecutive diagnostic imaging tests undergone by this population until 31 December 2018. We excluded: imaging tests that did not involve radiation exposure.

Main outcome measures The cumulative effective dose and the recurrent imaging tests by sex and age at entry of study.

Results Of the 224 751 people, 154 520 (68.8%) underwent an imaging test. The population had 1 335 752 imaging tests during the period of study: 1 110 077 (83.0%) plain radiography; 156 848 (11.8%) CT; 63 157 (4.8%) fluoroscopy and 5670 (0.4%) interventional radiography. 25.4% of the patients who had a CT, underwent five or more CTs (5.4% in the 0–20 years age group). The median total cumulative effective dose was 2.10 mSv (maximum 3980.30) and 16.30 mSv (maximum 1419.30 mSv) if we considered only doses associated with CT. Women received more effective dose than men (median 2.38 vs median 1.90, p<0.001). A total of 7142 (4.6%) patients received more than 50 mSv, with differences in men and women (p<0.001) and 2.5% of the patients in the 0–20 years age group, if we considered only doses associated with CT.

Conclusions Nearly 5% of patients received doses higher than 50 mSv during the 12-year period of study and 2.5% of the patients in the 0–20 years age group, if we considered only doses associated with CT. The rate of recurrent examinations was high, especially in older patients, but also relevant in the 0–20 years age group.

Strengths and limitations of this study

- This study follows the Basic Safety Standards Directive adopted by the European Union in 2013 in order to assess the amount of effective dose that patients receive during their lifetime.
- The analysis of medical records allowed us to evaluate all imaging tests performed in a cohort of 224 751 patients in routine practice during a 12-year study period, according to sex and age.
- The retrospective design did not allow a detailed assessment of the longitudinal nature of the exposure.
- Instead of recording the effective dose for each individual examination, we used the available evidence, as is proposed by the Dose DataMed project.
- The inclusion of a general hospital and its catchment area could have led to some limited generalisability in other settings.

INTRODUCTION

The use of ionising radiation in medicine provides valuable diagnostic information that undoubtedly benefits many patients. However, this radiation is also the greatest source of artificial radiation exposure.[1] In the last decades, there has been an increase in utilisation of X-rays, particularly of CT. Although a single CT scan does not present a significant risk for patients' health, each additional scan increases the potential for cancer-inducing biological damage[2] and patients may receive multiple CT scans over time.[3]

According to stochastic effect theory and based on the estimated incidence of fatal cancer from the International Commission of Radiation Protection (ICRP), as well as from the Biological Effects of Ionising Radiation Committee VII (BEIR VII), an effective dose of 100 mSv results in a risk of fatal cancer of approximately 1 in 200 in adults, and 1 in 100 for combined fatal and non-fatal cancer.[4] Moreover, although the BEIR VII report concludes that at doses lower than 100 mSv, the risk of cancer is small,[5] the Radiation Effect Research Foundation (RERF) in Japan, defends a 'linear-no-threshold' risk model, where the risk of cancer follows in a linear fashion at lower doses, without a threshold.

Smaller doses, therefore, have the potential to cause a small increase in cancer risk.[6]

A recent study in France[7] estimated that 0.7% of all new cancer cases in 2015 were attributable to medical ionising radiation. In Spain, a rate of 10.9 scans per 1000 children and young adults (0–20 years) was estimated in 2013, and a total of 168.6 cancer cases (95% CI 30.1 to 421.1) will be attributable to these CTs.[8]

Concern regarding the effects of ionising radiation from these medical tests on population health and the estimated increased risk of cancer for the population in general, and for children and young adults in particular (0–20 years)[9,10] has led to several initiatives to reduce the use of ionising radiation.

The Basic Safety Standards Directive was adopted by the European Union (EU) in 2013[11] to be transposed into national law by 6 February 2018. One key and innovative surveillance mechanism in this revised directive is to record the radiation dose received by each patient undergoing a medical imaging test. The directive mainly focuses on CT and tests involving interventional radiology, all of which are associated with a relatively high dose of radiation. Other diagnostic tests such as conventional radiography, however, are also frequently repeated in patients during their lives with a potential impact on health and could be included in these evaluations. However, these evaluations have not still been developed in the European countries as a systematically procedure.

A full evaluation of the radiation exposure from all medical diagnostic tests in Europe has been previously carried out in the project Dose DataMed I and II.[12,13] This project, based on national surveys, includes information on 36 European countries regarding population frequencies and radiation dose of X-ray and nuclear medicine radiodiagnostic tests. Although this project has led to a significant advance in the evaluation of population doses, we still do not have data regarding the cumulative dose in routine practice received by patients during long time periods. Some previous studies carried out in routine practice have evaluated the cumulative effective dose by focusing on specific pathologies,[14] population groups[15] or the effect of recurrent CT.[3] The previously mentioned study in France[7] assessed the cumulative exposure in adults of 30 years of age and older, using 2007 national frequencies of imaging tests and adjusted for changes in the use of these tests over time. However, none of them have evaluated the cumulative radiation exposure derived from all diagnostic tests carried out in routine practice during a long period of time, for both adults and children.

Given that the number of people who have these examinations many times during their lifetime has increased,[3] the detection of patients with high cumulative radiation derived from recurrent imaging tests will help clinicians to reduce patient-specific-associated cancer risks. Moreover, the identification of the clinical context of patients with high cumulative radiation doses due to repeat imaging could help clinicians to reduce the use of ionising radiation.[16] According to previous literature, patients with a diagnosis of neoplasm are prone to have recurrent imaging tests.[3]

The purpose of this study was to quantify the number of all radiological investigations performed in a cohort of patients in routine practice to calculate each patient's cumulative radiation exposure and the recurrent tests during a 12-year study period, according to sex, age, focusing on children and young adults (0–20 years) and imaging test. In addition, we identified the clinical context of patients with potentially high cumulative radiation risks.

METHODS

Study design

We conducted a retrospective cohort study to analyse the individual cumulative effective dose in routine practice and the recurrent imaging diagnostic tests.

Setting

The target population for the study were all residents in the catchment area of San Juan Hospital (Alicante), in the Valencian Community (Spain), a general centre, with a catchment population of 234 424 people. This is a referral hospital for all individuals living in the catchment area who belong to the National Health Care System (NHS). The majority of the Spanish population uses the NHS as the main medical service (the publicly funded insurance scheme covers 98.5% of the Spanish population) and hence, only a small percentage of patients are likely to have had imaging tests outside this setting.

Participants

We selected the population who belonged to the catchment area of that hospital during the year 2007, and collected all consecutive diagnostic imaging tests undergone by this population until 31 December 2018 (in any care setting, inpatient, outpatient or emergency department). Cohort members remained in the study until their exit date or they left the catchment area. We assigned each person to the unexposed group from the date of entry until the date of the first imaging test, and to the exposed group from the date of the first imaging test until the exit date. In addition, in those patients who did not account for the 12 years of follow-up, we assumed future practice estimating the proportion of imaging tests that would have been carried out during the remaining period if the patients had been in the cohort, except for the >80 years age group, where did not implemented this strategy given that the expectancy life in Spain is 82.83 years old.

We excluded: imaging tests that did not involve radiation exposure (ie, MRI and ultrasound) and patients who had an imaging test in this hospital but did not belong to its catchment area.

We classified the population in different age groups, and we focused our estimations in the 0–20 years old group due to their increased cancer risk.

In order to check generalisability of our data, we compare our population with Spanish population on the 31 December 2007.[17]

Imaging test frequency

We collected the following data from Medical Image Bank of the Valencian Community from the Department of Universal Health and Public Health Service: sex and age at entry in the study, radiological examination and date. Both the images and the patient data were anonymised and deidentified by the Health Informatics Department of the Hospital of San Juan using Research and Development (R&D) Cloud CEIB Architecture[7] This digital register started in 2007 in our setting.

According to previous studies,[3] each imaging test received was classified as a single radiation exposure. However, abdomen and pelvis tests carried out in the same process were included as a single abdomen–pelvis test, while an abdomen or pelvis test in a different process, even in the same patient, were included as two different tests. Thoracic and lumbar spine tests were included when they were performed alone but not when performed together with chest or abdominal tests.

Effective dose estimate

Given that it was impossible to get individual machine parameters for all imaging tests, we estimated the associated radiation effective dose per test according to its region of anatomical coverage by age and using previously published evidence[18] This review provides values of the typical effective doses associated with the 20 most frequent imaging tests for adults and children and for the most widely used set of weights (ICRP60) as well as for the most recent (ICRP103). We based our estimates on ICRP103, except in those cases where we did not have enough information. In addition, we estimated the effective dose of imaging tests different from the 20 most frequent imaging tests in Dose DataMed 2 project according to previous bibliography[19–21] (online supplementary tables 1 and 2).

Clinical classification of high-risk patients

We examined the clinical context of patients receiving the highest dose radiation. In accordance with previous studies,[3] we classified patients with diagnosis of neoplasm as patients at high risk of receiving high doses of radiation. We reviewed the digital register to establish which patients, who underwent an imaging test, had the ICD11 code of neoplasms (from 1993, when the register started, until the date of the first imaging test they underwent in our study).

Patient and public involvement

Patients and the public were not involved in the design, conduct and reporting of the research.

Statistical analysis

We estimated the imaging test frequency as the number of people having at least one test during the study period until the 31 December 2018 (final exposure status) and it was classified by sex and age. We also estimated the per-patient cumulative diagnostic imaging test during the period of study by adding up the number of tests received by each patient, and then evaluated the differences by sex and age group using the X^2 test. We also calculated the median and maximum number of imaging tests in our population and assessed the differences by sex and age using the Mann-Whitney U test.

Cumulative effective dose estimates were obtained by adding effective dose estimates received in each test in the patient's history. Data were expressed as the median, maximum and 25, 75, 95 percentiles. Differences by sex and age group were assessed using the Mann-Whitney U test.

We also classified the population according to the cumulative effective dose received during the period of study in the following way: 0–50 mSv, >50–100 mSv and >100 mSv[9] and evaluated the differences in these groups by sex and age group using the X^2 test.

We carried out a subgroup analysis to analyse the different cumulative effective dose in patients having CT and in those having plain radiograph (online supplementary file 1).

The statistical analyses of the data were performed with SPSS (V.25.0; SPSS). A p value of 0.05 was considered significant.

RESULTS

Cohort characteristics

The cohort included 232 446 people: 53.7% women and 46.3% men. The distribution by sex and age was similar to Spanish general population.

Of 232 446 people included in the cohort study, 154 520 (68.8%) underwent an imaging test associated with radiation during the period of study, with different frequency for men (69 265/107 622; 66.6%) and women (85 255/123 196; 70.6%) (p<0.001) (table 1). The number of people having at least one examination during the study period (defined as imaging test frequency) ranged from 56.5% in the 20–30 years age group to the highest percentage, 73.1%, in the 60–80 years group.

Characteristics of imaging tests undergone during period of study

Overall, the population had a total of 1 335 752 imaging tests during the period of study.

The type of imaging tests carried out were: 1 110 077 (83.0%) plain radiography; 156 848 (11.8%) CT; 63 157 (4.8%) fluoroscopy and 5670 (0.4%) interventional radiography. Men were more likely to have CT (14.3%) than women (10.1%) and women were more likely to have fluoroscopy (7.1%) than men (1.6) (p=0.035). Moreover, the percentage of people who had a CT increased with age (from 1.2% in the 0–5 years age group to 15.4% in the 60–70 years age group (table 2).

Table 1 Characteristics of study population by final exposure status (exposure status at end of study all study members were classified as unexposed on entry to the study), based on 12-year period of study (2007–2018) and comparison with Spanish general population on the 31 December 2007

Age at entry to study (years)	No (%) of people having at least one imaging test in the study*			Total no (%) of people in the study			Total no (%) of Spanish general population		
	Men	Women	Total	Men	Women	Total	Men	Women	Total
0 to 5	3938 (5.7)	3693 (5.3)	7631 (4.9)	5660 (5.3)	6564 (5.3)	12 224 (5.3)	1 287 417 (5.6)	1 213 658 (5.1)	2 501 081 (5.3)
>5 to 10	3798 (5.5)	3387 (4.9)	7185 (4.6)	5540 (5.1)	6425 (5.2)	11 965 (5.1)	1 259 447 (5.5)	1 181 161 (4.9)	2 440 613 (5.2)
>10 to 15	3611 (5.2)	3367 (4.9)	6978 (4.5)	5199 (4.8)	6031 (4.9)	11 230 (4.8)	1 269 835 (5.5)	1 194 802 (5.0)	2 464 643 (5.3)
>15 to 20	3581 (5.2)	3253 (4.7)	6834 (4.4)	5337 (5.0)	6189 (5.0)	11 526 (5.0)	1 188 946 (5.2)	1 113 600 (4.7)	2 302 551 (4.9)
>20 to 30	8520 (12.3)	9070 (13.1)	17 590 (11.4)	14 419 (13.4)	16 723 (13.6)	31 142 (13.4)	2 476 624 (10.8)	2 418 216 (10.1)	4 894 851 (10.4)
>30 to 40	11 318 (16.3)	16 291 (23.5)	27 609 (17.9)	19 116 (17.8)	22 171 (18.0)	41 287 (17.8)	3 239 875 (14.1)	3 248 190 (13.6)	6 488 079 (13.8)
>40 to 50	10 119 (14.6)	14 245 (20.6)	24 364 (15.8)	16 031 (14.9)	18 594 (15.1)	34 625 (14.9)	3 914 804 (17.0)	3 837 041 (16.0)	7 751 862 (16.5)
>50 to 60	8512 (12.3)	10 271 (14.8)	18 783 (12.2)	12 349 (11.5)	14 322 (11.6)	26 671 (11.5)	3 356 615 (14.6)	3 431 770 (14.3)	6 788 400 (14.5)
>60 to 70	7329 (10.6)	8764 (12.7)	16 093 (10.4)	10 199 (9.5)	11 829 (9.6)	22 028 (9.5)	2 439 786 (10.6)	2 650 101 (11.1)	5 089 898 (10.8)
>70 to 80	5997 (8.7)	8056 (11.6)	14 052 (9.1)	8901 (8.3)	10 324 (8.4)	19 225 (8.3)	1 614 748 (7.0)	1 975 175 (8.3)	3 589 930 (7.6)
>80	2542 (3.7)	4859 (7.0)	7401 (4.8)	4872 (4.5)	5651 (4.6)	10 523 (4.5)	959 627 (4.2)	1 662 367 (6.9)	2 621 998 (5.6)
Total (no/%)	**69 265** (**100.0**)	**85 255** (**100.0**)	**154 520** (**100.0**)	**107 622** (**100.0**)	**123 196** (**100.0**)	**232 446** (**100.0**)	**23 007 724** (**100.0**)	**23 926 081** (**100.0**)	**46 933 905** (**100.0**)

*P<0.05: differences in the number of people having at least one imaging test in the study by sex in all age groups and in the total.

Table 2 Number and percentage of each type of imaging test received, classified by sex and age during the period of study

Age at entry to study (years)	No (%) of plain radiography*			No (%) of CT*			No (%) of fluoroscopy*			No (%) of interventional radiography*		
	Men	Women	Total	Men	Women	Total	Men	Women	Total	Men	Women	Total
0–5	17 411 (3.7)	16 159 (2.6)	33 570 (3.0)	235 (0.3)	188 (0.2)	423 (0.3)	239 (2.6)	302 (0.6)	541 (0.9)	4 (0.1)	0	4 (0.1)
5–10	20 124 (4.3)	16 303 (2.6)	36 427 (3.3)	577 (0.7)	473 (0.6)	1050 (0.7)	362 (4.0)	286 (0.5)	648 (1.0)	8 (0.2)	6 (0.3)	14 (0.2)
10–15	20 053 (4.3)	15 280 (2.4)	35 333 (3.2)	955 (1.2)	748 (1.0)	1703 (1.1)	298 (3.3)	312 (0.6)	610 (1.0)	21 (0.6)	12 (0.5)	33 (0.6)
15–20	18 408 (3.9)	13 866 (2.2)	32 274 (2.9)	1070 (1.3)	780 (1.0)	1850 (1.2)	214 (2.3)	356 (0.7)	570 (0.9)	21 (0.6)	17 (0.7)	38 (0.7)
20–30	40 301 (8.6)	38 689 (6.1)	78 990 (7.2)	3162 (4.0)	3123 (4.1)	6285 (4.0)	617 (6.7)	1461 (2.7)	2078 (3.3)	58 (1.8)	69 (2.9)	127 (2.2)
30–40	57 707 (12.3)	74 139 (11.7)	131 846 (12.0)	6604 (8.3)	6597 (8.6)	13 201 (8.4)	1139 (12.4)	3165 (5.9)	4304 (6.8)	217 (6.6)	110 (4.6)	327 (5.8)
40–50	61 353 (13.1)	92 126 (14.5)	153 479 (13.9)	10 918 (13.7)	11 691 (15.2)	22 609 (14.4)	1347 (14.7)	11 746 (21.8)	13 093 (20.7)	401 (12.2)	208 (8.7)	609 (10.7)
50–60	67 366 (14.4)	99 223 (15.7)	166 589 (15.1)	16 560 (20.8)	14 070 (18.3)	30 630 (19.5)	1809 (19.8)	17 272 (32.0)	19 081 (30.2)	671 (20.4)	402 (16.9)	1073 (18.9)
60–70	75 355 (16.1)	109 588 (17.3)	184 943 (16.8)	19 665 (24.6)	16 763 (21.8)	36 428 (23.2)	1754 (19.2)	12 611 (23.4)	14 365 (22.7)	981 (29.8)	582 (24.4)	1563 (27.6)
70–80	67 088 (14.3)	110 800 (17.5)	177 888 (16.2)	15 925 (20.0)	16 302 (21.2)	32 227 (20.5)	1130 (12.3)	5799 (10.7)	6929 (11.0)	766 (23.3)	743 (31.2)	1509 (26.6)
>80	22 730 (4.9)	47 008 (7.4)	69 738 (6.3)	4125 (5.2)	6317 (8.2)	10 442 (6.7)	250 (2.7)	688 (1.3)	938 (1.5)	140 (4.3)	233 (9.8)	373 (6.6)
Total (n/%)	**467 373** (**100.0**)	**631 917** (**100.0**)	**1 110 077** (**100.0**)	**79 796** (**100.0**)	**77 052** (**100.0**)	**156 848** (**100.0**)	**9159** (**100.0**)	**53 998** (**100.0**)	**63 157** (**100.0**)	**3288** (**100.0**)	**2382** (**100.0**)	**5670** (**100.0**)

*P<0.05: differences by sex in in all age groups and in the total.

Recurrent imaging tests

The population exposed undergone a median of 5 imaging tests and 52.9% of the patients underwent five or more examinations. Women were more likely to have more cumulative imaging tests than men during this period (maximum 221 in men and 633 in women; IQR 2–10 in men and 2–12 in women, p<0.001).

Table 3 shows distribution data for per-patient imaging tests (median and maximum) by age and sex for each type of imaging test.

Moreover, 8.2% of the patients who had an imaging test during the period of study and 25.4% (12 602/49 544) of the patients who had a CT, underwent five or more CTs (5.5% (174/3187) in the 0–20 years age group), with a maximum of 75 examinations; 1.8% of the patients who had an imaging test and 9.7% (2849/29 314) of the patients who had a fluoroscopy examination, underwent five or more fluoroscopy examinations (1.9% (28/1478) in the 0–20 years age group), with a maximum of 18 examinations; 0.2% of the patients who had an imaging test and 5.8% of the patients who had an interventional radiography, underwent three or more interventional radiographies, with a maximum of 10 examinations, and 21.2% of the patients who had an imaging test and 21.6% (32 778/151 980) of the patients who had a plain radiography, underwent 10 or more plain radiographies (10.1% (2849/28356) in the 0–20 years age group), with a maximum of 559 examinations.

Men were more likely to have more than five CTs than women (27.8% vs 23.3%, p<0.001), and less likely to have more than five fluoroscopy examinations (2.3% vs 11.6%, p<0.001) and more than 10 plain radiographies than women (19.6% vs 23.2%, p<0.001, respectively) (data not shown).

Cumulative effective dose received during the period of study

The median total cumulative effective dose including all imaging tests in all population exposed was 2.10 mSv (maximum 3980.30). Women received more effective dose than men (median 2.38 vs median 1.90, p<0.001). The cumulative effective dose increased with age: median 0.72 (maximum 47.15) in the 0–5 years age group and median 10.20 (maximum 3980.309) in the 70–80 years age group (p<0.001) (table 4).

If we consider the cumulative effective dose associated with plain-radiograph (online supplementary table S3), the median total cumulative effective dose was 0.70 mSv (maximum 2112.79). There were also differences by sex: women received more effective dose than men (median 1.02 vs median 0.64, p<0.001).

Considering the cumulative effective dose associated with CT (online supplementary table S4), the median total cumulative effective dose was 16.30 mSv (maximum 1419.30). Men received more effective dose than women (median 19.80 vs median 13.20, p<0.001). 2.5% of the patients in the 0 to 20 group received more than 50 mSv.

A total of 4844 (3.1%) people received cumulative doses between 50 and 100 mSv and 2298 (1.5%) people received doses greater than 100 mSv. Men were more likely to have cumulative effective dose above 50 mSv (both between 50 and 100 mSv (3.5%) and higher than 100 mSv (1.8%), than women (2.9% and 1.2%, respectively) (p<0.001). Of the 2298 patients who received more than 100 mSv during the 12-year study period, 725 (33.3%) were patients in the 60–70 years age group; 565 (24.6%) were patients in the 50–60 years age group; 462 (20.1%) were patients in the 70–80 years age group and 350 (15.2%) were patients in the 40–50 years age group (table 5).

If we consider the cumulative effective dose associated with plain radiograph, almost 100% of people received cumulative effective dose below 50 mSv. Considering the cumulative effective dose associated with CT, 17.8% of people received doses above 50 mSv (8.2% above 100 mSv).

Classification of high-risk patients

Of the 154 520 patients who had an imaging test during the period of study, 11 072 (7.1%) had a diagnosis of cancer during the period of study. Out of 2298 patients who received more than 100 mSv, 1678 (73.0 %) had a diagnosis of cancer, compared with 43.14% of patients who received between 50 and 100 mSv and 4.9% of patients who received less than 50 mSv.

DISCUSSION

This study provides an important information on the cumulative radiation dose received by patients in routine practice. We showed that the median cumulative effective dose including all the imaging tests during the 12-year study period was 2.10 mSv (maximum 3980.30). However, the median cumulative effective dose associated with only CT was 16.30 (maximum 1419.30).

The median cumulative effective dose was, therefore, lower than the 100 mSv threshold often considered for significant risks in stochastic theory.[22] Nevertheless, 4844 (3.1%) people received between 50 and 100 mSv and 2298 (1.5%) more than 100 mSv during the study period. In addition, 17.8% of people who had CTs received doses above 50 mSv and 8.2% of them, doses above 100 mSv. A previous study evaluated CT use in general practice during an 8-year period (1998–2005) and showed that nearly 50% of the population had CT and 1.2% of them received doses >100 mSv. The longer follow-up period in our study (12 vs 8 years) does not justify the much higher cumulative effective dose associated with CT shown in our patients.

However, our frequencies are lower than those reported in a previous study where 15% received estimated cumulative effective doses of more than 100 mSv.[3] This study included adult patients who had received CT during the previous 22 years while our cohort study included general population. In addition, we only showed data from a 12-year period, so the percentage of patients with an effective dose higher than 100 mSv during their lifetime

Table 3 Cumulative diagnostic imaging tests per person exposed by sex and age during the period of study

Age at entry to study (years)	Plain radiography (median/maximum)			Computed tomography (median/maximum)			Fluoroscopy (median/maximum)			Interventional radiography (median/maximum)		
	Men	Women	Total	Men	Women	Total	Men	Women	Total	Men	Women	Total
0–5	3 (40)	3 (41)	3 (41)	1 (4)	1 (5)	1 (5)	1 (8)	1 (7)	1 (8)	1 (1)	–	1 (1)
5–10	4 (40)	4 (86)	4 (86)*	1 (17)	1 (11)	1 (17)	2 (8)	1 (5)	2 (8)	1 (2)	1 (1)	1 (2)
10–15	4 (72)	3 (49)	4 (72)*	1 (11)	1 (11)	1 (11)*	1 (8)	1 (5)	1 (8)*	1 (7)	1 (3)	1 (7)
15–20	4 (47)	3 (64)	3 (64)*	1 (14)	1 (13)	1 (14)*	1 (6)	1 (6)	1 (6)	1 (2)	1 (2)	1 (2)
20–30	3 (165)	3 (62)	3 (165)*	1 (36)	1 (21)	1 (36)	1 (5)	1 (7)	1 (7)*	1 (3)	1 (9)	1 (9)
30–40	3 (112)	3 (80)	3 (112)*	1 (29)	2 (39)	1 (39)*	1 (8)	1 (10)	1 (10)*	1 (4)	1 (3)	1 (4)
40–50	4 (101)	4 (373)	4 (373)*	1 (44)	2 (57)	2 (57)*	1 (7)	2 (13)	2 (13)*	1 (6)	1 (5)	1 (6)
50–60	5 (160)	7 (95)	6 (160)*	2 (62)	2 (49)	2 (62)*	1 (18)	2 (13)	2 (18)*	1 (7)	1 (5)	1 (7)
60–70	7 (213)	9 (173)	8 (213)*	2 (71)	3 (75)	2 (75)*	1 (10)	2 (14)	2 (14)*	1 (9)	1 (6)	1 (9)
70–80	8 (139)	10 (559)	9 (559)*	2 (69)	3 (74)	2 (69)*	1 (8)	1 (11)	1 (11)*	1 (10)	1 (7)	1 (10)
>80	6 (85)	7 (101)	7 (101)*	2 (23)	2 (35)	2 (35)*	1 (5)	1 (8)	1 (8)*	1 (4)	1 (5)	1 (5)
Total	**4 (213)**	**4 (559)**	**4 (559)***	**2 (71**	**2 (75)**	**2 (75)***	**1 (18)**	**2 (14)**	**2 (18)***	**1 (10)**	**1 (9)**	**1 (10)**

*P<0.05.

Table 4 Cumulative effective dose (MSV) per person exposed during the period of study

Age at entry to study (years)	Total			Men			Women			
	Median	Percentile 25–75	Maximum	Median	Percentile 25–75	Maximum	Median	Percentile 25–75	Maximum	P value
0–5	0.21	0.06–1.60	47.15	0.20	0.06–1.28	37.38	0.21	0.06–1.93	47.15	0.579
5–10	0.48	0.03–2.38	94.58	0.42	0.04–2.26	94.58	0.52	0.02–2.48	55.19	0.128
10–15	0.67	0.06–2.64	196.16	0.64	0.06–2.56	196.16	0.77	0.07–2.78	143.51	0.001
15–20	0.74	0.10–2.98	159.51	0.65	0.10–2.80	159.51	0.83	0.10–3.08	104.15	0.001
20–30	1.00	0.11–4.02	222.27	0.69	0.10–3.18	222.27	1.38	0.22–4.83	221.10	<0.001
30–40	1.23	0.38–5.75	297.14	1.09	0.16–5.14	297.14	1.29	0.38–6.04	259.56	0.002
40–50	2.00	0.38–10.12	716.16	2.03	0.30–10.87	389.44	1.96	0.38–9.70	716.16	0.417
50–60	4.27	0.64–17.08	629.58	4.17	0.62–18.05	629.58	4.32	0.65–16.26	430.68	0.514
60–70	8.35	1.47–25.72	506.08	9.80	1.47–29.21	506.08	7.63	1.48–23.46	489.57	<0.001
70–80	10.20	2.40–26.00	3980.30	12.05	2.60–30.46	502.08	8.81	2.18–23.21	3980.30	<0.001
>80	5.30	1.19–15.96	204.32	6.54	1.28–18.98	183.80	5.00	1.10–4.58	204.32	<0.001
Total	**2.10**	**0.36–10.15**	**3980.30**	**1.90**	**0.2–10.20**	**629.58**	**2.38**	**0.38–10.10**	**3980.30**	**<0.001**

Table 5 Number and percentage of people exposed according to the cumulative effective dose during the period of study

Age at entry to study (years)	Total (no, percentage)			Men (no, percentage)			Women (no, percentage)			
	0 to 50 mSv	>50 to 100 mSv	>100 mSv	0 to 50 mSv	>50 to 100 mSv	>100 mSv	0 to 50 mSv	>50 to 100 mSv	>100 mSv	P value
0–5	7631 (100.0)			3938 (100.0)			3693 (100.0)			
5–10	7179 (99.9)	6 (0.1)		3793 (99.9)	5 (0.1)		3386 (100.0)			0.135
10–15	6953 (99.6)	21 (0.3)	4 (0.3)	3597 (99.6)	11 (0.3)	3 (0.1)	3356 (99.7)	10 (0.3)	1	0.647
15–20	6814 (99.7)	17 (0.2)	3 (0.1)	3570 (99.7)	9 (0.3)	2 (0.1)	3244 (99.7)	8 (0.2)	1	0.884
20–30	17 450 (99.2)	97 (0.6)	43 (0.2)	8462 (99.3)	39 (0.5)	19 (0.2)	8988 (99.1)	58 (0.6)	24 (0.3)	0.227
30–40	27 145 (98.3)	353 (1.3)	111 (0.4)	11 101 (98.2)	158 (1.4)	59 (0.5)	16 044 (98.5)	195 (1.2)	52 (0.3)	0.011
40–50	23 358 (95.9)	656 (2.7)	350 (1.4)	9678 (95.6)	295 (2.9)	146 (1.4)	13 680 (96.0)	361 (2.5)	204 (1.4)	0.193
50–60	17 201 (91.6)	1017 (5.4)	565 (3.0)	7681 (90.2)	506 (5.9)	325 (3.8)	9520 (92.7)	511 (5.0)	240 (2.3)	<0.001
60–70	14 045 (87.3)	1323 (8.2)	725 (4.5)	6227 (85.0)	694 (9.5)	408 (5.6)	7818 (89.2)	629 (7.2)	317 (3.6)	<0.001
70–80	12 490 (88.9)	1101 (7.8)	462 (3.3)	5151 (85.9)	594 (9.9)	252 (4.2)	7339 (91.1)	507 (6.3)	210 (2.6)	<0.001
>80	7113 (96.1)	253 (3.4)	35 (0.5)	2425 (95.4)	96 (3.8)	21 (0.8)	4688 (96.5)	157 (3.2)	14 (0.3)	0.003
Total	**147 379 (95.4)**	**4844 (3.1)**	**2298 (1.5)**	**65 623 (94.7)**	**2407 (3.5)**	**1235 (1.8)**	**81 756 (95.9)**	**2437 (2.9)**	**1063 (1.2)**	**<0.00**

will be even higher. Moreover, according to linear theory, smaller doses have the potential to cause a small increase in cancer risk.[6] However, the cancer rates did not change in our cohort during the period of study.

Previous research focused on patients <20 years of age[23] showed that of the 22 867 patients who had CT during an 8-year period, 1.6% received doses higher than 50 mSv. In our cohort study, the percentage was lower, but we included all imaging tests (radiography and CT). In the subgroup analysis by type of imaging test, we observed higher rates in the CT group in the 0–20 years age group (2.5%). Greater efforts to decrease the number of recurrent CTs in children have to be implemented, taking into account that a recent study showed that even low doses of ionising radiation increase the risk of childhood leukaemia.[24]

These results, which show high rates of population undergoing imaging tests, are in line with the DoseData Med II project,[3] in which Spain had one of the greatest frequency of imaging tests per 1000 population in comparison with the European average.

We also found high rates of recurrent CT (25.4% of the patients who had a CT, underwent five or more CTs, with a maximum of 75 examinations). Previous studies have shown higher rates of recurrent CT (33% of patients underwent five or more CT examinations),[6] but they included a longer followed-up period (22 vs 12 years). Moreover, 5.8% of the patients who had an interventional radiography, underwent three or more interventional radiographies during the period of study, with a maximum of 10 examinations. Both interventional radiography and CT are associated with a relatively high dose of radiation. Plain radiography and fluoroscopy, although they are not associated with such high doses, also showed a high recurrent rate. Additional measures should be applied to control these recurrent rates, particularly to subgroups who are more prone to recurrent controls such as patients with chronic diseases like cancer.

In fact, as in previous studies,[3] most of the patients who received more than 100 mSv had previous history of malignancy. However, 27% of them had no underlying malignant disease. In both groups of patients, clinicians should balance the risk of the cumulative exposure against the benefit of recurrent imaging.

Most of our population younger than 20 years old received effective dose lower than 50 mSv during the period of study; however, more than 40% of this population underwent five or more imaging tests during this period and 5% of them had five or more CTs. Moreover, the maximum number of plain radiography, CT, fluoroscopy and interventional radiography examinations undergone was 86, 17, 8 and 7, respectively, in this age group. The linear no-threshold model is very controversial and is considered of little relevance for doses below 100 mSv; nevertheless, we have to take into account that children are more sensitive to ionising radiation effects due to their high radiosensitivity.[25 26] In addition, previous studies have shown a possible risk of cancer from radiation associated with commonly used tests, such as CT scan, in children at very young ages.[27]

There is increasing international interest in reducing radiation doses from imaging tests.[28] Previous studies have shown difficulties when implementing initiatives to reduce radiation exposure into clinical practice. For instance, communication with patients regarding associated risk is essential to get a rational use of diagnostic imaging test, but there is a lack of knowledge in the general population regarding radiation exposure and the associated risks related to these tests.[29 30] In addition, recent studies showed that most clinicians were unaware of radiation exposure associated with imaging tests[31–33] and that less than 50% of the imaging tests carried out in clinical practice were considered appropriate according to the available recommendations and 29.1% of the total collective effective dose was associated with inappropriate imaging tests.[34]

Assessing the amount of effective dose that patients receive during their lifetime, as the European Commission of Radiological Protection recommends,[11] could, therefore, be considered a useful tool to raise awareness among clinicians and patients regarding the risks associated, and to help them to reach a shared decision when asking for imaging tests to reduce cancer risk. However, an effort should be made to reduce the great variation in CT protocols, technical parameters and radiation doses across countries.[35]

Limitations of our study included the retrospective design and lack of information regarding patients who might have been imaged outside the healthcare system, as well as radiation derived from nuclear medicine that also represents a relevant proportion of the collective population dose.[12 13] However, as we stated previously, the publicly funded insurance scheme covers 98.5% of the Spanish population and only a small percentage of patients are likely to have had imaging tests outside this setting.

Moreover, given that we studied the imaging tests carried out during a 12-year period, some patients could have been lost to follow-up. Based on practice during this 12-year period, we estimated the proportion of imaging tests that would have been carried out during the remaining period if the patients had been in the cohort.

We used the available evidence to estimate the effective dose for each imaging test, as is proposed by the DoseData Med project.[12 13] However, this type of estimation has inherent limitations; it does not take into account the test date, the scanner model or the patient's characteristics. Nevertheless, it does not affect the overall result. It is also true that our results may differ from those of studies in different settings. We used effective dose to quantify the radiation exposure associated with each imaging test instead of organ doses. Absorbed organ doses are important for some procedures that either involve high doses or include sensitive tissues in the primary radiation beam.[4] However, our aim was not to assess cancer risks associated with medical ionising radiation but to compare across the different imaging tests carried out in our population.

We included a general hospital and its catchment area (with a total population over 200 000 people). Even though our results could have some limited generalisability in other settings, analysing this population provides important insights, showing as far as we know, the first evaluation of the cumulative effective dose in routine practice (including adults and children) according to age and sex over a 12-year period. In addition, as we showed in the result section, the population included in this study is similar to general Spanish population.

CONCLUSIONS

A total of 4844 (3.1%) people received cumulative doses between 50 and 100 mSv and 2298 (1.5%) people received doses greater than 100 mSv during the 12-year period of study. Considering only the doses associated with CT, 2.5% of the patients in the 0–20 years age group received doses above 50 mSv. Moreover, the rate of recurrent examinations was high, especially in older patients, but also relevant in the 0–20 years age group. These data could help clinicians to make an informed decision when asking for each imaging test, which would lead to lower cumulative lifetime radiation, and consequently a reduction in associated risks.

Contributors BLL, IG-A and JMS conceived of and designed the study. BLL and JMS acquired the data. BLL and JMS prepared the data and BLL, JMS and IG-A interpreted statistical analyses. BLL did the statistical analyses and drafted the data tables. BLL, JMS and IG-A cowrote the manuscript. All authors critically revised the paper for important intellectual content and approved the final version.

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