

A Study on the of Justification of Low Dose Chest Computed Tomography during Health Examinations

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Abstract

Background: In this study, the justification after evaluating the hazards and benefits of a low-dose chest CT scan in a physical examination was investigated as follows. **Methods/Statistical Analysis:** 502 people who had undergone a CT scan as part of a regular medical checkup and with no clinical symptoms at H hospital, located in Gyeonggi Province, Korea during the period from January to December, 2013 were dichotomized to two groups of those aged under 40 and those aged 40 years or more. **Results:** Those aged 40 or more who underwent a lung CT test for the first time accounted for 53% (266/502) and those under age 40 accounted for 20.5%(103/502) of their corresponding age groups. The ultimate purpose of CT tests is the early detection of lung cancer. Eight patients were discovered to have lung cancer and their characteristics were as follows. All were male and the youngest was 44 years old. The average number of calcified nodules in those with a non-calcified nodule was 1.00 those under 40 and 1.58 for of 40 or older, which was also a significant difference ($p<0.05$). But overall chest CT in this situation was not found to be justified based on considerations of the balance between the benefits of CT and the overall risk of radiation exposure. **Conclusion:** In order to secure justification, routine chest CT should be conducted from an age of 40 or at an earlier age in those with a smoking history.

Keywords: Calcification, ICRP, Low Dose CT, Lung Cancer, Nodule, NSLT, Screening

1. Introduction.

The clinical usage of Computed Tomography (CT) has increased greatly since its development in 1972¹. It was first introduced to Korea in 1977, and has since become one of the most essential diagnostic modalities. With the emergence of MULTIPLE row Detectors CT (MDCT), the technology now rapidly and conveniently provides high definition diagnostic information. In 2012 there were a total of 1854 CT units in Korea or 37 devices per 1 million of the population, which ranked Korea fifth among OECD countries².

Due to this increase and the cost of CT units, the number of imaging tests performed have increased

continuously, but at the same time it is being emphasized that unnecessary patient exposure to radiation should be avoided^{3,4}.

At present, if deemed necessary by the doctor responsible for diagnosis and treatment, there is no limit on the number of CT scans that can be taken. However, greater consideration of individual patients is required in order to minimize exposure to radiation. Diagnostic CT tests are the most basic tests performed and are covered by the national health insurance, but unfortunately this has led to abuse, and has increased radiation exposures⁵.

What is more worrisome is that with an increased interest in health, patients tend more so to opt for CT without a doctor's recommendation or diagnosis, even

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when they are in good health, for the early discovery of cancer. As of 2011 the mortality rate of cancer in Korea (per 100,000 of the population) was highest for lung cancer (31.7 people), followed by liver cancer (21.8), stomach cancer (19.4), and colorectal cancer (15.4)⁶.

Due to the developments in diagnostic equipment and in the medical check-up programs offered by national health insurance or by corporate health insurance, the number of optional CT tests performed is increasing. In cases where optional tests, such as, radiation tests are used to verify whether a specific disease is existent, patients know little of the risks associated with exposure to radiation and are provided with inadequate information. In cases where optional CT tests in other categories are conducted or where tests are conducted regularly, the justification principle states that the benefits conferred should be more than enough to offset the potential risks posed by radiation exposure. However, this principle is often violated. The National Cancer Information Center suggests that an age of 40 for men and women should be considered the starting point for CT tests targeting the detection of early lung cancer⁷. But in recent years increased interest in health means that such tests are being conducted routinely on individuals younger than 40. This study was performed on individuals who had undergone optional CT as part of a regular medical check-up based on personal decision and did not have any clinical symptoms. The study subjects were categorized based on age as younger than 40 or 40 or older to determine the diagnostic effectiveness of CT and to provide future directions regarding the use of CT.

2. Methodology

2.1 Study Subjects

502 people who had undergone a CT scan as part of a regular medical checkup and with no clinical symptoms at H hospital, located in Gyeonggi Province, Korea during the period from January to December, 2013 were dichotomized to two groups of those aged under 40 and those aged 40 years or more.

2.2 Image Analysis

CT was conducted without contrast media from lung apex to lung base. Images were retrospectively analyzed by a radiologist who determined the numbers and sizes of nodules and the presence of calcification. Nodule sizes were categorized as smaller than 5mm, from 5 to

10mm, or 10mm or larger. Diseases were categorized into bullae (bleb), inflammatory region, tuberculosis, vascular disease, atelectasis, and cancer. The difference in nodule distributions by gender was analyzed using the student's t-test and the general and diagnostic characteristics of the patients were cross-analyzed compared.

3. Results

3.1 Analysis of Nodules According to Age

286 subjects (57%) had more than one calcification or a non-calcified nodule, whereas the remaining 216 (43%) did not. 49 subjects (20.2%) age under 40 had a calcified nodule and 5 (11.6%) had a non-calcified nodule. 332 non-calcified nodules were found in these 286 patients. 57 were under the age of 40 and 275 were 40 or over.

In total 65 calcified nodules were found, of which 5 were in subjects less than 40 and 60 were in subjects of 40 or older. The average numbers of non-calcified nodules present in those with a non-calcified nodule were 1.16 for those under 40 and 1.43 for of 40 or older, which was a significant difference ($p < 0.05$) (Table 2).

The average number of calcified nodules in those with a non-calcified nodule was 1.00 those under 40 and 1.58 for of 40 or older, which was also a significant difference ($p < 0.05$) (Table 1).

Table 1. Analysis of nodules according to age unit: n, < >: patient number

	≥ 40 years	Over 40 years	Mean	SD	p-value
Non- Calcification	57(±0.37) <49>	275(±0.52) <194>	1.38	0.503	.000
Calcification	5(±0.00) <5>	60(±0.72) <38>	1.51	0.703	.000

3.2 General and Diagnostic Analysis of Nodules

Of the 502 study subjects, 449 (89.4%) were men and 53 (10.6%) were women. Among those under the age of 40, 120 (23.9%) were men and 6 (1.2%) were women ($p < 0.05$) (Table 2). In terms of the sizes of non-calcified nodules among those under 40, 15.6% (38/243) were under 5mm, 9.0% (9/243) were between 5mm and 10mm, and 0.8%(2/243) were 10mm or larger, and among those aged 40 or over, 53.9%(131/243) were under 5mm, 21.0% (51/243) were nodules between 5mm and 10mm, and 4.9%(12/243) were

larger than 10mm (Table 2). The distribution of calcified nodules in what population revealed that the occurrence rate prevalence was low before age 40, but for those of 40 or over were substantially higher, that is, 65.1%(28/43) for

nodules smaller than 5mm and 20.9% (9/43) for nodules between 5mm and 10mm, indicating that most nodules were smaller than 10mm (Table 2).

Table 2. General and diagnostic analysis of nodules (): unit

		≥ 40 years	Over 40 years	p-value
Sex (patient number)	Male	120 (23.9)	329 (65.5)	.014
	Female	6 (1.2)	47 (9.4)	
Nodule size - Non calcified (n)	5mm under	38 (15.6)	131 (53.9)	.413
	5mm~10mm	9 (3.7)	51 (21.0)	
	10mm over	2 (0.8)	12 (4.9)	
Nodule size - Calcification (n)	5mm under	3 (7.0)	28 (65.1)	.583
	5mm~10mm	1 (2.3)	9 (20.9)	
	10mm over	1 (2.3)	1 (2.3)	
Diagnosed disease (patient number)	Bullae, Bleb	8 (5.8)	41 (29.5)	.286
	Inflammatory region	10 (7.2)	45 (32.4)	
	Tuberculosis	4 (2.9)	8 (5.8)	
	Vascular disease	1 (0.7)	6 (4.3)	
Lung Screening (patient number)	Atelectasis	5 (3.6)	11 (3.2)	.031
	1 year	20 (4.0)	74 (14.7)	
	2 year	1 (0.2)	6 (4.3)	
	3 year over first	2 (0.4)	17 (3.4)	
		103 (20.5)	266 (53.0)	

Those aged 40 or more who underwent a lung CT test for the first time accounted for 53% (266/502) and those under age 40 accounted for 20.5% (103/502) of their corresponding age groups. Those who had undertaken the CT examination one year earlier accounted for 14.7% (74/502) of those aged 40 or more and 4% (20/502) of those aged less than age 40. A small number of subjects had undergone the CT examination two years previously or three or more years previously (Table 2).

4	M	48	20mm	smoking history	Over 10 years	10~20
5	M	52	4mm	smoking	Over 30 years	more than 20
6	M	53	15mm	smoking history	Over 10 years	more than 20
7	M	58	13mm	no smoking	none	20
8	M	71	8mm	smoking	Over 30 years	more than 20 years

Table 3. Analysis of diagnosis of lung cancer patients

No	Sex	Age	Size	Smoking	Smoking period	Number of the day smoking
1	M	44	9mm	smoking	Over 20 years	more than 20
2	M	45	4mm	smoking	Over 20 years	10~20
3	M	45	5mm	smoking	Over 20 years	more than 20

The ultimate purpose of CT tests is the early detection of lung cancer. Eight patients were discovered to have lung cancer and their characteristics were as follows. All were male and the youngest was 44 years old. With the exception of two patients, nodules were 5mm or larger, and excepting one patient, 7 patients had been smoking more than 10 cigarettes a day for 10 years or more, thus providing more evidence of the high correlation between smoking and lung cancer (Table 3).

4. Discussion and Conclusion

CT equipment is used in many clinical situations because of its practical benefits. In order to recoup the costs of CT equipment, medical institutions have been increasing the number of tests performed, but unnecessary exposure of patients to radiation needs to be curbed. According to a paper published by Brenner et al. in the *New England Journal of Medicine*, 1.5-2.0% of cancers in the US are attributable to radiation exposure during CT, which has drawn the attention of the medical community to the risks of radiation exposure from CT⁸. When using radiation for medical purposes, benefits, the risks involved, perceptions of results, perceptions of alternative results, and alternative methods need to be considered before deciding on CT. The ICRP defines the concept of justification regarding radiation protection as “not opting for exposure to radiation when it is not accompanied by sufficient benefits to the individual”. However, the usage of CT tests for the early detection of lung cancer in patients without any clinical symptoms continues to increase. If such tests are conducted without a doctor’s recommendation in consideration of specific diseases that may or may not be existent, given lack of patient awareness regarding the risk of radiation exposure, then it is likely that patients will be exposed to undue risks. For diseases with a high mortality rate, such as lung cancer, CT tests are commonly used for early detection. Studies on the use of CT for diagnosing lung cancer, and in particular the National Lung Screening Trial (NLST) conducted in the US, have shown that compared to X-ray imaging, CT examinations reduce the mortality rate from lung cancer by more than 20%⁹.

As an initial method for diagnosing lung cancer, X-ray imaging plus sputum examination four times in randomized clinical trials, but no reduction in the mortality rate was observed as compared with X-ray imaging alone. During the period year to 2002, a series of reports issued on the diagnosis of lung cancer by CT, noted that CT has about a three-fold higher diagnosis rate for lung cancer than chest X-ray. In order to assess the clinical significance of lung cancer diagnosis using CT, a NLST was carried out from August 2002 to September, 2007 on individuals categorized as high risk for lung cancer, that is on subjects between the ages of 55 and 74 who had smoked for at least 30 “pack-years” and what was found. A study on lung cancer diagnosis by CT was

conducted in Japan by Sone on subjects aged 40 or over that had never smoked and subjects of the same age that had smoked more than one pack-year and what was found¹⁰. A study by Chong et al. conducted in Korea on CT usage for lung cancer diagnosis was performed on subjects of 45 years and over with more than 20 pack-years and what was found¹¹. Opinions differ regarding CT usage, but in a clinical setting no guidance is available concerning the merits of CT in terms of reducing lung cancer mortality when it is used more than once per annum. Furthermore, no recommendation has been made regarding the maximum allowable number of health check CT lung cancer examinations. Lung cancer diagnosis using CT has a three-fold higher positive diagnosis rate than chest X-ray, and thus, has a higher false positive rate, which leads to higher medical costs and test-associated complications. There are also cases where lung cancer is over-diagnosed. It is of particular concern that lung cancer can actually be caused by radiation exposure, and in smokers the carcinogenic effect of radiation is greater. Previous studies have been conducted on those at high risk of lung cancer development, but no study has been performed on routine CT usage in healthy people of different ages. The National Cancer Information Center recommends starting chest CT at age 40 or above for men and women (or at an earlier age if the individual is a smoker) and also recommends one annual examination only for smokers.

The recommendation issued by The Korean Society of Thoracic Radiology also states that diagnostic CT examinations for lung cancer should be performed once a year for those between the ages 55 and 74 who are smokers with more than 30 pack-years, are current smokers, or have quit smoking for less than 15 years. The association does not recommend routine diagnostic CT examinations for lung cancer for those with other than a high risk of the disease¹².

In the present study, the usage of chest CT during medical check-ups was analyzed at a university hospital. The analysis performed shows that more than 25% of examinations were conducted on individuals less than 40. Even if the effective radiation dose of chest CT is 1.5 mSv, which is less than that normally delivered, it could have a huge effect on public health due to collective increases in radiation exposure. Such increases in the usages of self-determined optional tests are caused by various reasons, such as, lack of awareness of the risks of radiation,

patients' demands, lack of professional consultation, and the pursuit of profits. In order to reduce unnecessary radiation exposure, the justification of chest CT needs to be secured based on proper consideration of its merits and demerits, unless a specific recommendation is made by a doctor. I believe that such consideration would serve as a basis for the ethicality of medical practice.

This analysis of chest CT usage on asymptomatic patients during health check-ups for the early detection of lung cancer was conducted by dichotomizing subjects about an age of 40. The numbers of nodules detected in younger and older subjects were significantly different, but overall chest CT in this situation was not found to be justified based on considerations of the balance between the benefits of CT and the overall risk of radiation exposure. In order to secure justification, routine chest CT should be conducted from an age of 40 or at an earlier age in those with a smoking history. Furthermore it is important that patients, especially those aged under 40 years, be provided with sufficient information regarding the radiation risks posed by CT.

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