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1. Overview of the paper

Thyroid screening examination was started in all Fukushima residents age 18 or younger in October 2011 after the March 2011 Tokyo Electric Fukushima Daiichi nuclear power plant accident following the Great East Japan Earthquake and Tsunami. The first round screening (Initial Screening) conducted during FY 2011 through FY 2013 was completed, and the second round screening (Full-Scale Screening) is underway in FY 2014 and FY 2015. Ever since February 2013, the examination results have been released to the public, in Japanese as well as English, on the Fukushima Prefecture website. However, no epidemiological analysis has been carried out on the released data, leading to extremely insufficient conditions for causal inference, public health and clinical policy planning, future outlook and information disclosure to residents.

The Okayama University team used standard epidemiological methods to analyze released data, and submitted the results as an original article to *Epidemiology*, official journal of the International Society of Environmental Epidemiology. I would like to report here that the article has been accepted and published online ahead-of-print.

【Original article】Thyroid Cancer Detection by Ultrasound among Residents Aged 18 Years and Younger in Fukushima, Japan: 2011 to 2014

http://journals.lww.com/epidem/Abstract/publishahead/Thyroid_Cancer_Detection_by_Ultrasound_Among.99115.aspx#

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Abstract

Background: After the Great East Japan Earthquake and Tsunami in March 2011, radioactive elements were released from the Fukushima Daiichi Nuclear Power Plant. Based on prior knowledge, concern emerged about a consequential increased incidence of thyroid cancer among exposed residents.

Methods: After the release, Fukushima Prefecture performed ultrasound thyroid screening on all residents aged ≤18 years. The first round of screening included 298,577 examinees (as of December 31, 2014), and a second round began in April 2014. We analyzed the prefecture results from the first and second round up to December 31, 2014, in comparison with the Japanese annual incidence and the incidence within Fukushima Prefecture.

Results: The highest incidence rate ratio, using a latent period of 4 years, was observed in the Central Middle District of the prefecture compared with the Japanese annual incidence (incidence rate ratio = 50; 95% confidence interval: 25, 90). The prevalence of thyroid cancer was 605 per million examinees (95% CI: 302, 1,082) and the prevalence odds ratio compared with the reference district in Fukushima Prefecture was 2.6 (95% CI: 0.99, 7.0). In the second screening round, even under the assumption that the rest of examinees were disease-free, an incidence rate ratio of 12 has already been observed (95% CI: 5.1, 23).

Conclusions: An excess of thyroid cancer has been detected by ultrasound among children and adolescents in Fukushima Prefecture within 4 years of the release, and is unlikely to be explained by a screening surge.

2. Significance of publication of the paper and the issue of screening effect and the overdiagnosis discourse

This analysis revealed that thyroid cancer incidence within three years of the accident increased by several tens of times in Fukushima residents who were age 18 or younger at the time of the accident in comparison to the Japanese annual incidence, and that it would be impossible to attribute the increase to reasons other than radiation, such as the screening effect or overdiagnosis. According to discussions by some specialists, screening effect refers to *detection of so-called "true cancer" 2-3 years earlier than it would be diagnosed clinically*. Overdiagnosis refers to *detection due to screening of so-called "false cancer," or a mass of cancer cells, which may never be clinically diagnosed as cancer in life*. In many of the ongoing discussions, these two — screening effect and overdiagnosis — are collectively called "screening effect," with its meaning mainly referring to the definition of "overdiagnosis" stated above.

Our analysis reveals that the thyroid cancer incidence at the end of 2014 far exceeds the 15-year thyroid cancer risk estimated in the *WHO Health risk assessment from the nuclear accident after the 2011 Great East Japan earthquake and tsunami* released in late February 2013. Moreover, while a tendency towards excess occurrence of thyroid cancer was beginning to be observed in Chernobyl in 1987 — the year after the accident, this analysis actually showed ultrasound screening allowed detection of an increased incidence of thyroid cancer within one year.

I will now explain why the screening effect and overdiagnosis are not valid explanations for excess detection of thyroid cancer cases. First, the thyroid cancer incidence rate calculated in our analysis is 20-50 times the pre-accident rate. This is an order of magnitude higher than the increased incidence in thyroid cancer due to causes other than radiation exposure reported in the past. The effect generally called "screening effect" results in the incidence rate about several times higher than the pre-screening rate in cancers including thyroid cancer. It is impossible to explain the increased incidence this high by causes other than radiation.

Next, despite repeated statements that there is no precedence of mass screening and follow-ups in populations with little exposure such as Initial Screening in Fukushima, studies have been published on the results of ultrasound screening in Chernobyl conducted in children and adolescents who were conceived and born post-accident or who lived in areas with relatively low levels of contamination. A total of 47,203 underwent screening, with not a single case of thyroid cancer detected. Although the age range slightly differs from screening in Fukushima Prefecture, this result cannot be explained by differences in the level of sophistication of ultrasound equipment in detecting 5 mm nodules.

Author	Time of investigation	Age of subjects in the investigation	Area of the investigation	Number Of subjects	Thyroid Cancer cases	Prevalence $_{6}$ (95%C.I.)per 10
Demidchik et al. *1	2002	14 years old and under	Gomel (born after 1987)	25,446	0	0 (0-145)
Shibata et al.*2	1998-2000	8-13 years old	Gomel (born after 1987)	9,472	0	0 (0-389)
Ito et al.*3	1993-1994	7-18 years old	Mogilev (relatively low contaminated)	12,285	0	0 (0-300)
Total				47,203	0	0 (0-78)

*1: Demidchik YE et al. : Childhood thyroid cancer in Belarus, Russia and Ukraine after Chernobyl and at present. Arq Bras Endocrinol Metab 2007; 51: 748-762.

*2: Shibata Y et al: 15 years after Chernobyl: new evidence of thyroid cancer. Lancet 2001; 358: 1956-1966.

*3: Ito M et al: Childhood thyroid diseases around Chernobyl evaluated by ultrasound examination and fine needle aspiration cytology. Thyroid 1995; 5(5): 365-368.

Moreover, geographical variations in cancer detection rates (prevalence rates) within Fukushima Prefecture cannot be explained by the screening effect or overdiagnosis. Also, the emerging results of the second round screening point to the increased incidence rate which is already about 20 times higher than the pre-accident rate even under the assumption of large underestimation. When data released on August 31, 2015 are analyzed by areas and districts, it becomes apparent incidence rates in some areas and districts are beginning to exceed the first round incidence rates. As cases detected due to screening effect and overdiagnosis should have been harvested (harvesting effect), it is suggested the effect of radiation exposure due to the accident is beginning to appear within Fukushima Prefecture.

In addition to overdiagnosis, a claim of overtreatment is often made. However, the post-surgical data of thyroid cancer cases operated at Fukushima Medical University, shows there is no evidence that premature or excessive surgeries were conducted, with the exception of 3 cases where patients and/or their families opted for voluntary surgery despite an option of non-surgical observational follow-up. Rather, the data suggests the fast progression of cancer in the operated cases. I am going to introduce an excerpt of the document titled, "Regarding Surgically Indicated Cases," released by Professor Shinichi Suzuki of Fukushima Medical University.

Regarding Surgically Indicated Cases (translated by Dr. Yuri Hiranuma)

"As of March 31, 2015, 104 among those eligible for thyroid examination underwent surgery after being diagnosed to have "malignant or suspicious" tumors in the confirmatory examination. 97 cases were operated on at the Division of Thyroid and Endocrine Surgery, Fukushima Medical University and 7 at other facilities. As 1 of 97 cases turned out to be a benign nodule post-operatively, 96 thyroid cancer cases are discussed here. According to the pathological evaluation, 93 cases were papillary thyroid cancer and 3 were poorly differentiated thyroid cancer. (…) The post-surgical pathological diagnosis revealed 28 cases (29%) with tumor diameter ≤ 10 mm, excluding 14 cases with mild extrathyroidal extension. And 8 cases (8%) had no lymph node metastasis, extrathyroidal extension, or distant metastasis (pT1a pN0 M0). Of all 96 cases, mild extrathyroidal extension (pEX1) was seen in 38 cases (39%), and lymph node metastasis was positive in 72 cases (74%). "

https://www.pref.fukushima.lg.jp/uploaded/attachment/129308.pdf
http://fukushimavoice-eng2.blogspot.com/2015/09/surgical-and-pathological-details-of.html

3. Perspectives and reactions of international epidemiologists

Starting with the *WHO Health Risk Assessment*, the majority of experts expected an increase in thyroid cancer incidence in Fukushima Prefecture after the accident. As a result, there was no strong opposition to the results of our analysis. We have analyzed newly released data and presented the results at the annual conferences of the International Society for Environmental Epidemiology (ISEE) in Basel in 2013, Seattle in 2014, and San Paulo in 2015. Our presentation drew a big interest, and the results of our analysis have been accepted without any issues other than astonishment about how high the rate is. This reaction made us feel that there is a large gap between the international expert opinions and the explanation of screening effect and overdiagnosis in Japan.

4. Recommendations as a public health specialist

So far, hardly any radiation protection measures have been discussed other than evacuation in Fukushima Prefecture. Therefore, many recommendations can be presented given the results of our analysis. There is no reason not to prepare for the increased incidence at a full pace anticipated beyond 5 years after the accident or other expected situations. At present time, administrative bodies should urgently establish and implement countermeasures, including media relations, rather than discussing whether thyroid cancer cases have actually increased or not, or their causal relationship with radiation exposure.

First, in preparation for the potential increase in thyroid cancer cases after the fourth post-accident year, medical resources should be checked to ensure that they are fully equipped. It appears that Fukushima Medical University owns a medical robotic system — the daVinci surgical system — which is supposed to eliminate visible scars of thyroid surgery. Its use should be considered even though it is not covered by the national health insurance.

Next, an attempt should be made to keep track of thyroid cancer cases in an expansive and well-developed manner, including cases in Fukushima residents 19 or older at the time of the accident or cases outside Fukushima Prefecture.

Furthermore, the current assessment of thyroid cancer cases relies only on ultrasound screening. As time goes on, participation is likely to decline. A medical record booklet system such as the Hibakusha booklet should be established and the cancer registry should be well-developed in cooperation with prefectural and municipal medical associations.

In addition, we need to prepare for and begin assessment and investigation of cancer other than thyroid cancer, such as leukemia, breast cancer and other solid cancers which are expected to increase according to the WHO Health Risk Assessment. Minimum latency period for blood-borne malignant neoplasms such as leukemia has already passed. Also, I believe it is necessary to investigate non-cancer illnesses and prepare to deal with them.

Of course, it is necessary to gather further evidence to conduct a more detailed analysis of incidence data of thyroid cancer and other illnesses in Chernobyl. Also, dose estimation for radioactive iodine should be reconsidered due to an excess occurrence of thyroid cancer beyond the estimation by WHO.

Naturally, the resettlement plan to return evacuees to areas with an air dose rate of 20 mSv/year should be postponed for the time being. If the resettlement plan is based on a scientifically incorrect statement, “Radiation-induced cancer does not occur, or is undetectable even if it occurs, under the exposure dose of 100 mSv,” then that’s all the more reason for the plan to be halted and reconsidered.

As the air dose rate is still quite high, a more meticulous plan by age should be urgently prepared, although this has hardly been discussed in the past. In other words, further radiation protection measures should ideally be planned and implemented, including temporary evacuation plans for pregnant women, infants, toddlers, children, adolescents, and women with pregnancy potential, in that order.

Lastly, I would like to discuss explanations consistently given in Fukushima Prefecture such as, “Cancer incidence will not increase due to the Fukushima nuclear accident” or “Even if cancer incidence increases, it will not be detectable.” These statements are only validated if both of the following two conditions hold true: 1) There is no (excess) occurrence of radiation-induced cancers below the exposure dose of 100 mSv; 2) Exposure dose in Fukushima Prefecture never exceeded 100 mSv, and all the exposure doses were much below 100 mSv. These two conditions

have prevented most of discussions regarding realistic and cost-conscious radiation protection measures.

But condition 1 is not even scientifically accurate, and no experts inside or outside Japan will make such a statement nowadays. And condition 2 is not accurate since the thyroid equivalent dose was estimated to exceed 100 mSv in residents outside the 20 km zone according to the WHO Preliminary Dose Estimation report released in 2012, which became the basis of the 2013 WHO Health Risk Assessment report. Our analysis showed results which appear to far exceed the 15-year thyroid cancer risk in the WHO Health Risk Assessment.

However, it has only been four and a half years since the nuclear accident. Considering the average latency period for thyroid cancer and the time trend of excess occurrence of thyroid cancer in Chernobyl, it is highly likely that new thyroid cancer cases might appear every year at a 10 to 20 times higher rate than the last four and a half years. Under such a circumstance, a swift correction of statements by the government is needed: otherwise, trust will be lost, resulting in disruption to responses and measures to the reality. I hope our study will provide an opportunity to review announcements and response plans of the government. Current situations will only worsen anxiety, mistrust, and damages due to baseless rumors.

Please refer to slides in the supplementary material for a summary of data released by Fukushima Prefecture on August 31, 2015.

(English translation by Dr. Yuri Hiranuma)