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< Review >

Results of the first-round thyroid examination of the Fukushima Health Management Survey

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Abstract

After the accident occurred at the Tokyo Electric Power Company's Fukushima Daiichi Nuclear Power Plant, the Fukushima Health Management Survey (FHMS) was initiated. The FHMS consists of a basic survey and four detailed surveys: a thyroid ultrasound examination, a comprehensive health check, a mental health and lifestyle survey, and a pregnancy and birth survey. In this article, we briefly summarized whether an association exists between radiation exposure and the observation of thyroid cancer cases according to the results of the first-round thyroid examination in the FMHS. Regarding this issue, Tsuda and his colleagues showed an association using an internal comparison (odds ratio (OR)=2.6, 95% confidence interval (CI): 0.99-7.0) and an external comparison (incidence rate ratio =50, 95% CI : 25-90). However, for this internal comparison, Ohira and his colleagues used two ways of objective classifications of districts in Fukushima; (1) the group of municipalities of which proportion of the exposed external dose level of more than 5 mSv was higher than or equal to 1% (≧1% of 5 mSv), the group of municipalities of which proportion of the exposed external dose level less than 1 mSv was higher than or equal to 99.9% (≧99.9% of 1m Sv<99%), and others, and (2) the location groups applied by WHO. For the classification (1), they obtained OR=1.49 (95% CI : 0.36-6.23) from the highest group to the lowest, which was similar to the results of the classification (2). For the external comparison, Takahashi and his colleagues developed a cancer-progression model with several sensitivities under non-accident conditions, and showed 116 cases were possible to observe in Fukushima under non-accident conditions. Katanoda and his colleagues found an observed/expected ratio of 30.8 (95%CI: 26.2-35.9) of the prevalence of thyroid cancer among residents aged ≦ 20 years (160.1 observed of cases and 50.2 expected cases), and a cumulative number of thyroid cancer deaths in Fukushima Prefecture of 0.6 under age 40 with the same method. This large disparity implied the possibility of over-diagnosis in thyroid examinations.

A researcher reported the results were unlikely to be explained by a screening effect, which implied the association between thyroid cancer cases and external radiation exposure. However, subsequently, a possibility that it might be a result of over-diagnosis of the thyroid examinations was pointed. And, no significant associations were found by applying objective classification of districts and by raising comparability with the incidence data of whole Japan, respectively. In the Basic Survey of FHMS, only individual external doses in the first four months after the accident has been observed. So neither external dose after the four months nor internal dose was applied in these studies. Further studies are necessary to clarify the existence of the association by applying the estimation of individual overall thyroid dose.

keywords: thyroid examination, Fukushima health management survey, thyroid cancer, radiation external exposure, the first-round survey

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I. Introduction

The Great East Japan Earthquake occurred on 11 March 2011. Tokyo Electric Power Company's Fukushima Daiichi Nuclear Power Plant was damaged by a tsunami, which caused radiation emission outside of the plant. The Fukushima prefectural government charged Fukushima Medical University with planning and conducting a survey, named the Fukushima Health Management Survey (FHMS), to relieve anxiety and promote the long-term health of the residents of Fukushima prefecture. The FHMS consists of a basic survey and four detailed surveys: a thyroid ultrasound examination, a comprehensive health check, a mental health and lifestyle survey, and a pregnancy and birth survey. In this article, we briefly summarized the association between radiation exposure and the observation of thyroid cancer cases in the FHMS from the results of the first-round thyroid examination in FMHS.

1. The Basic Survey (radiation dose estimation) [1]

The Basic Survey is a questionnaire survey which targets all the residents (approximately 2,050,000) as of 11 March 2011. Each external radiation dose was estimated based on the recorded movements of the respondents in the four months after the accident. The overall effective response proportion to the basic survey, for the entire population of Fukushima Prefecture, was 27.6% (566,680 of 2,055,267) (31 March 2017) as shown in Table 1. The individual external radiation exposure was estimated using the external dose estimation system for Fukushima residents by the National Institute of Radiological Sciences (NIRS). The doses were estimated by adding the product of the time data for the residents' behaviors and the dose rate to the map [2]. The NIRS external system has applied the System for Prediction of Environmental Emergency Dose Information and monitoring data reported officially by the government.

Table 1 Response proportions to the Basic Survey

			Response proportion (%)
Targets		2055267	100.0
	Original questionnaire	493538	24.0
	Simplified questionnaire	73142	3.6
Responders	Total	566680	27.6

As of 31 March 2017

Modification of Table 1 from the Basic Survey [1] (radiation dose estimation)

2. Thyroid ultrasound examination (preliminary baseline screening) [3]

The target population is the residents of Fukushima Prefecture aged 0-18 years as of 11 March 2011 (born between 2 April 1992 and 1 April 2011). The thyroid ultrasound examination was planned with a cohort study design [4] in which the subjects were monitored routinely (at 2-year intervals in those ≦20 years old, and at 5-year intervals in those >20 years old), because the Chernobyl accident resulted in an excess emergence of thyroid cancer four years after the accident. The examination consists of (i) a primary complete survey and secondary confirmatory examinations; (ii) a detailed ultrasound examination [3]; and (iii) fine-needle aspiratory cytology (FNAC). In the primary examination, ultrasonography was applied to examine the thyroid gland, and examination specialists assessed the image on the basis of the following criteria. Criteria A: Those with

Table 2 Primary thyroid examination screening

	Target population (N)	Participants (N)	Proportion (%)	Results				
				N (%)	A1 (%)	A2 (%)	B (%)	C (%)
FY2011	47769	41810	87.5	41810 (100.0)	26375 (63.1)	15214 (36.4)	221 (0.5)	0 (0.0)
FY2012	161123	139337	86.5	139337 (100.0)	76194 (54.7)	62155 (44.6)	987 (0.7)	1 (0.0)
FY2013	158757	119326	75.2	119326 (100.0)	52036 (43.6)	66205 (55.5)	1085 (0.9)	0 (0.0)
Total	367649	300473	81.7	300473 (100.0)	154605 (51.5)	143574 (47.8)	2293 (0.8)	1 (0.0)

Number and proportion of participants with nodules/cysts

Participants		Results			
		Nodules		Cysts	
		≧5.1 mm	≦5.0 mm	≧20.1 mm	≦20.0 mm
FY2011	41810	219 (0.5)	230 (0.6)	1	15139 (36.2)
FY2012	139337	973 (0.7)	730 (0.5)	9	62267 (44.7)
FY2013	119326	1083 (0.9)	753 (0.6)	2	66493 (55.7)
Total	300473	2275 (0.8)	1713 (0.6)	12	143899 (47.9)

Modification of Table 1 and Table 2 from Thyroid Ultrasound Examination (Preliminary Baseline Screening) [3] test results of A1 (no nodules / cysts) and A2 (nodules ≦ 5.0 mm or cysts ≦20.0 mm) were recommended for watchful waiting until they undergo the next screening. Criteria B: Those with B (nodules ≧5.1 mm or cysts ≧20.1 mm) were advised to take the Confirmatory Examination. Criteria C: Those with immediate needed for a confirmatory examination [3]. In secondary confirmatory examinations, we conducted ultrasonography, blood tests, urine tests, and FNAC if it was necessary for those with B or C test results. We recommended medical follow-up for those requiring it on the basis of their confirmatory test results.

3. Results of the first-round thyroid examination [3]

According to the primary examination, the participation proportion was 81.7% (300,473 of 367,649) as shown in Table 2. The number of participants with A1 or A2 test results was 298,179 (99.2%), the number with B results was 2,293 (0.8%), and only 1 had C results. According to the confirmatory examination, 2,293(92.9%) were recommended for further testing and 2,090 of them (98.1%) participated in it. Of 2,090 participants, the number of those who met A1 or A2 primary diagnostic criteria (including those with other thyroid conditions) were 132 with A1 and 579 with A2, respectively. They were advised to take their next regularly scheduled examination (Full-scale thyroid screening program). 1,379 (66.0%) participants with neither A1 nor A2 results were recommended to have medical follow-up after 6 to 12-months, or were advised to take their next regularly scheduled examination. Of 1,379 participants, 547 (39.7%) underwent FNAC.

II. Findings from first-round thyroid examination of the FHMS

In February 2018, more than 25 articles based on the FHMS data were published. They are listed at http://fmu-global.jp/publications-n/, which contained four articles that explored the association between radiation exposure and the emergence of thyroid cancer. Here we summarized them.

1. Study by Shimura and colleagues [5]

This study showed that the proportion to detect thyroid nodules and cancer increased in age, but showed a peak at 11 to 12 years in cysts, and that the prevalence proportion of thyroid nodules and cancers were different in sex, but its difference of cysts was small. They summarized this results by the description of the age and sex distributions of the thyroid ultrasound examinations of children and adolescents in the FHMS. In this study, 294,905 participants aged≦18 years at the time of the accident received primary thyroid ultrasound examinations from October 2011 through March 2014, and 2032 subjects participated in secondary confirmatory examination in the first round of the FHMS. The evaluation of the age- and sex-specific prevalence and size of thyroid cysts, nodules, and cancers showed that thyroid cysts, nodules, and cytologically suspected cancers were found in 68,009, 1415, and 38 male subjects and in 73,014, 2455, and 74 female subjects, respectively.

2. Study by Tsuda and colleagues [6]

The first-round of screening included 298,577 examinees. In this study, the data up to December 31, 2014, were used and compared with the Japanese annual incidence and the incidence in four areas in Fukushima Prefecture. The highest incidence rate ratio (IRR), with their assumption of a latency period of 4 years, was estimated (IRR = 50, 95% confidence interval (CI): 25-90) in the central middle district of the prefecture compared with the Japanese annual incidence of the national cancer registry (NCR) (external comparison). The prevalence proportion of thyroid cancer (605 per million, 95% CI : 302-1082) and the prevalence odds ratio (OR=2.6, 95% CI : 0.99-7.0) were compared with the reference district in Fukushima Prefecture (internal comparison). They concluded that an excess of thyroid cancer had been detected by ultrasound among children and adolescents in Fukushima Prefecture within 4 years of the release, and was unlikely to be explained by a screening effect.

3. Study by Katanoda and colleagues [7]

After Tsuda's paper was published, Katanoda and his coauthors calculated the observed/expected (O/E) ratio of thyroid cancer prevalence for the residents aged≦20 years. The observed prevalence was the number of thyroid cancer cases detected by the thyroid examination in FHMS until April 2015. They calculated the expected prevalence as the cumulative incidence as determined by a life-table method using the national estimates of the thyroid cancer incidence rate in 2001-10 and the population of Fukushima Prefecture. Under the assumption that there was neither a nuclear accident nor a screening intervention, an O/E ratio of 30.8 (95% CI: 26.2-35.9) was determined as shown in Table 3. The cumulative number of thyroid cancer deaths under age 40 in Fukushima Prefecture was 0.6. Combined with the existing knowledge regarding the effect of radiation on thyroid cancer, their descriptive result of disparities between them suggested the possibility of over-diagnosis.

4. Study by Ohira and colleagues [8]

Applying a cross-sectional study design with 300,476 participants aged 18 years and younger who underwent

Table 3 Observed and expected thyroid cancer prevalence in Fukushima Prefecture, as of the end of 2014

	Sex	Number of malignant cases[a]	Percentage among target population	O/E ratio	95%CI
Observed (age at screening ≦20[b])	Males	54.8	0.032		
	Females	105.3	0.064		
	Total	160.1	0.047		
Expected (attained age ≦20)					
Based on average incidence rate[c]	Males	1.2	0.001	46.1	34.5-59.8
	Females	4.0	0.002	26.6	21.7-32.0
	Total	5.2	0.002	30.8	26.2-35.9
Based on average incidence rate[d]	Males	1.3	0.001	41.4	31.0-53.7
	Females	5.9	0.004	17.9	14.6-21.6
	Total	7.2	0.002	22.2	18.9-25.9

O/E, observed/expected; CI, confidence interval

a: Including suspected malignancy.

b: Corrected for age-specific screening rate.

c: Calculated using the national incidence rate between 2001 and 2010.

d: Calculated using the national incidence rate extrapolated to 2014 using the average annual percent change between 2001 and 2010.

Reprint of Table 1 from Katanoda K, et al. (2016) [7]

Table 4 Age- and sex-adjusted ORs and 95% CIs of thyroid cancer according to location group by first 4-month external radiation doses estimated by The Fukushima Health Management Survey

	Group A[a)]	Group B[b)]	Group C[c)]
N	4192	213564	82720
Women, %	50.5	49.4	49.8
Age at the time of the nuclear accident, y (SD)	9.4 (5.4)	9.0 (5.1)	8.6 (4.8)
Age at the time of the screening, y (SD)	10.2 (5.4)	10.6 (5.1)	11.2 (4.9)
Duration from the nuclear accident to the time of the screening, y (SD)	0.8 (0.6)	1.7 (0.7)	2.6 (0.5)
No. of cases	2	76	34
Prevalence proportion per 100000 people	47.7	35.6	41.1
Crude OR (95%CI)	1.16 (0.28-4.83)	0.87 (0.58-1.30)	Reference
Age- and sex- adjusted OR (95%CI)[d)]	1.49 (0.36-6.23)	1.00 (0.67-1.50)	Reference
Multivariable-adjusted OR (95%CI)[e)]	1.01 (0.22-4.63)	0.82 (0.51-1.34)	Reference

a) The group of the proportion of exposed external radiation of 5 mSv or more is more than or equal to 1%.

b) The group of the proportion of exposed external radiation of 5 mSv or more is less than 1 % and of 1 mSV or less is less than 99.9%.

c) The group of the proportion of exposed external radiation of 1 mSv or less is more than or equal to 99.9%.

d) Adjusted for age at the thyroid examination and sex.

e) Adjusted for age at the thyroid examination, sex, and duration from the nuclear accident to the thyroid examination.

95% CI=95% confidence interval, OR=odds ratio, SD=standard deviation

Reprint of Table 2 from Ohira T, et al. (2016) [8]

thyroid examinations between October 2011 and June 2015, Ohira and his colleagues used two ways of objective classifications of districts in Fukushima; (1) the group of municipalities which proportion of the exposed external dose level of more than 5 mSv was higher than or equal to 1% (≧1% of 5m Sv), the group of municipalities which proportion of the exposed external dose level less than 1 mSv was higher than or equal to 99.9% (≧99.9% of 1m Sv<99%), and others, and (2) the classification by WHO [9]. The prevalence proportions of thyroid cancer for the three groups (1) were 47.7/100,000 for the highest dose area, 35.6/100,000 for the middle dose area, and 41.1/100,000 for the lowest dose area, respectively. It showed that the highest and the middle dose areas had OR=1.49 (95% CI: 0.36-6.23) and 1.00 (0.67-1.50), respectively, using the lowest dose areas as a reference (internal comparison) as shown in Table 4 by using logistic regression models adjusting for age and sex. For the classification (2), the groups were characterized as relatively

Table 5 Expected detected cases determined by the model with several sensitivity values

Sensitivity (primary mass screening)	Sensitivity (secondary confirmation examination)	Males (Observed cases n=39)		Females (Observed cases n=77)	
		Expected detected cases	95%CI	Expected detected cases	95%CI
1.0	1.0	49.3	35.5-63.0*	141.1	117.8-164.4
0.9	1.0	44.3	31.3-57.4*	127.0	104.9-149.1
0.9	0.9	39.9	27.5-52.3*	114.3	93.4-135.3
0.9	0.8	35.5	23.8-47.2*	101.6	81.9-121.4
0.8	1.0	39.4	27.1-51.7*	112.9	92.1-133.7
0.8	0.9	35.5	23.8-47.2*	101.6	81.9-121.4
0.8	0.8	31.5	20.5-42.5*	90.3	71.7-108.9*
0.7	1.0	34.5	23.0-46.0*	98.8	79.3-118.3
0.7	0.9	31.0	20.1-42.0*	88.9	70.4-107.4*
0.7	0.8	27.6	17.3-37.9	79.0	61.6-96.5*
0.6	1.0	29.6	18.9-40.2*	84.7	66.6-102.7*
0.6	0.9	26.6	16.5-36.7	76.2	59.1-93.3*
0.6	0.8	23.7	14.1-33.2	67.7	51.6-83.9*
0.5	1.0	24.6	14.9-34.4	70.6	54.1-87.0*
0.5	0.9	22.2	12.9-31.4	63.5	47.9-79.1*
0.5	0.8	19.7	11.0-28.4	56.5	41.7-71.2*

*Observed cases are included in the 95% CI of the expected cases.
95%CI=95% confidence interval
Modification of Table 4 from Takahashi H, et al. (2017) [10]

highest dose area, middle dose area, relatively lowest dose area with OR=1.50 (95% CI: 0.37 - 6.15) and OR=1.01 (95% CI: 0.69 - 1.47), respectively. From these results, the external radiation dose was not associated with thyroid cancer prevalence among Fukushima children within the first 4 years after the nuclear accident.

5. Study by Takahashi and colleagues [10]

In this study, a common model applicable to any region in Japan under non-accident conditions was built, and the expected prevalence was estimated using simulation of the sensitivity of the first-round thyroid examination. To adjust for age, a cancer-progression model that was an extension of Day and Walter's was assumed. By minimizing the weighted root mean squared error between the average age-specific thyroid incident rates from 2001 to 2010 in the NCR and those determined by the model, the expected detectable prevalent cases were obtained by the model with their examination-participation proportions, and several sensitivities were simulated. The simulation results showed that the numbers of observed prevalent cases were within the 95%CI of the expected prevalent cases with several sensitivities in each gender as shown in Table 5. These results implied that the number of observed thyroid cancer cases can be detected by the FHMS first-round thyroid screening at several sensitivities under non-accident conditions. They also estimated that the median sojourn times between the detectable incidence and clinical incidence were 34 years (males) and 30 years (females), respectively.

III. Summary

With regard to the association between radiation exposure and cancer detection, Tsuda and colleagues showed that the maximum prevalence proportion of thyroid cancer among areas in Fukushima expressed as a ratio with the reference district in Fukushima (internal comparison) was estimated to be 2.6. They also showed that the incidence rate was 50 times as high as that estimated by the national cancer registry (external comparison). This was a shocking result, but there were questions about the legitimacy of the estimation methodology. Nine scientific letters were immediately sent in response to the article to question the justification of their results [11-19]. For example, the results might have arisen due to screening effect or over-diagnosis, and thus did not reflect the association between radiation exposure and the incidence. And they pointed several technical questions in their article with regard to the process of estimation.

The first was their procedure by which the districts were grouped. Whether were the districts classified objectively or not? The more frequently they tried grouping, the more often statistical significance they would find (i.e., a type I error). Second, whether was their comparison of the data between FHMS and NCR valid? The prevalence proportion (with the unit of no-dimension) was obtained from the thyroid examinations in FHMS, but the incidence rate (with the unit of 1/time) was obtained from NCR. To unify the unit, they applied a basic formula: P (prevalence proportion)

=I (incidence rate)×D (disease duration), which holds in a steady-state disease pool [20]. They assumed 4 years for the disease duration (their latent duration) of childhood thyroid cancer, corresponding to the time between the Fukushima accident and thyroid cancer detection, for which the maximum duration was 3 years and 10 months. The point is whether they did check "steady-state disease pool" or not. Furthermore, the data applied by them were obtained from the first-round survey, which was the baseline study of the cohort study of the thyroid examinations in FHMS. According to the evidence from the Chernobyl accident, thyroid cancer in children and adolescents increased 5 years after the accidents [21-22], but the first-round thyroid examination of the FHMS was conducted in the first 3 years. It is likely that the cancer detected in the first-round examination does not reflect the incident cases caused by the radiation exposure, but seems the original prevalent cases observed independently of the exposure.

Ohira and colleagues showed the results when the first questionable point was corrected by applying two ways of objective classifications of districts. Both results showed no significance between the external radiation and thyroid cancer prevalence among Fukushima children within the first 4 years after the nuclear accident.

Takahashi and colleagues showed the results when the second questionable point was corrected by raising the comparability of both data as modifying three points, to use a common index for adjusting units between data of FHMS and NCR, to develop a cancer-progression model for adjusting age, and to simulate the sensitivity of the thyroid examinations. They successfully built a cancer-progression model of thyroid cancer based on Japan's NCR data under non-accident conditions, they were able to adjust the units and age between data, and they simulated sensitivity for the comparison. The results implied that the detected thyroid and its suspected 116 cases in the first-round screening examination was possible to observe with several sensitivities under non-accident conditions.

Katanoda and their colleagues compared NHMS with NCR. They applied a cumulative incidence rate for unit unification. Under the assumption that there was neither a nuclear accident nor a screening intervention, two results, namely an O/E ratio of 30.8 (95% CI: 26.2-35.9) and the cumulative number of thyroid cancer deaths in Fukushima Prefecture being 0.6 under age 40, implied the possibility of over-diagnosis in the thyroid examination. There is another report over-diagnosis was considered by the disparity of longitudinal tendency between incidence rate (rapid increase) and mortality rate (stable) of thyroid cancer in South Korea, 1993-2011 [23].

Since the thyroid examinations in FHMS started, people have been worried that many cases were detected by the thyroid examinations. For this situation, a researcher reported the results were unlikely to be explained by a screening effect, which implied the association between thyroid cases and external radiation exposure. However, subsequently, a possibility that it might be a result of over-diagnosis of the thyroid examinations was pointed. And, no significant associations were found by applying objective classification of districts and by raising comparability with the incidence data of whole Japan, respectively. In the Basic Survey of FHMS, only individual external doses in the first four months after the accident has been observed. So neither external dose after the four months nor internal dose was applied in these studies. Further studies are necessary to clarify the existence of the association by applying the estimation of individual overall thyroid dose.

Conflict of Interest

There are no conflict of interest.

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Results of the first-round thyroid examination of the Fukushima Health Management Survey

福島県民健康調査甲状腺検査先行検査の結果について

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抄録

福島東京電力原子力発電所事故後,福島県民健康調査（FHMS）がスタートした．この調査は基本調査，甲状腺検査，健康診査，こころの健康度・生活習慣に関する調査，妊産婦に関する調査から構成されている．この論文では，放射線被ばくと甲状腺がんとの関連が存在するかどうかについての検討を先行検査（１巡目検査）の結果から簡潔にまとめる．津田らの研究は県内の地域間比較（オッズ比OR=2.6，95％ 信頼区間（CI）：0.99-7.0）と日本全体の発生状況との外的比較（罹患率比（IRR）= 50，95％ CI : 25-90）を示し，関連性の存在をアピールした．しかし地域間比較については大平らが２通りの客観的な分類として，（1）5 mSvより高い外部線量の割合が１％以上である市町村からなるグループ, 1 mSvより低い外部線量の割合が99.9％以上である市町村からなるグループ,その他）と，（2）WHOにもって用いられた地域，をそれぞれ用いた．分類（1）では，外部線量の最も高い群の最も低い群に対するオッズ比OR=1.49（95％ CI : 0.36-6.23）を得，これは分類（2）でも同様であった．外的比較については，高橋らが，事故がない仮定のもとで，がんの進展モデルと甲状腺検査の感度を用いて，事故がない状況であっても福島県において116人の患者を検出しうることを示した．片野田らの研究では福島県における事故後の累積罹患率の期待度数（5.2人）と観測度数（160.1人）の比30.8（95％ CI: 26.2-35.9）と累積死亡数（40歳以下で0.6人）の大きな乖離から，甲状腺検診の過剰診断の可能性を示唆している．

このように，今回の放射線事故に関する放射線被ばくと甲状腺がんとの関連については，はじめに関連が示唆された結果が発表されたものの，それは過剰診断の可能性により生じている可能性が指摘され，その後客観的な分類，比較可能性等を考慮した研究により，これらの関連は否定されている．しかし，県民健康調査の甲状腺検診では事故後４か月間の外部被ばく線量の値のみが得られており，そのため事故後４か月以降の外部被ばく線量や内部線量はこれらの研究では用いられていない．個人個人の総被ばく線量の推定値を用いて関連の有無を明らかにする研究がさらに必要とされている．

キーワード：甲状腺検査，福島県民健康調査，甲状腺がん，放射線外部被ばく, 1巡目検査（先行検査）