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Protocol and Progress of a Thyroid Study in the Epidemiological Study of Health Effects in Fukushima Emergency Workers

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Abstract

Objective: To describe the protocol and progress of a thyroid study using thyroid ultrasonography in emergency workers who responded to the Fukushima nuclear accident.

Methods: Thyroid ultrasonography was performed on Fukushima emergency workers at over 60 health examination institutions. The accuracy of ultrasonography is controlled by standard procedural protocols, examiner training, and a central review system. Thyroid findings are classified into 4 categories: Category A1 (no nodule or cyst), Category A2 (nodules ≤ 5.0 mm and/or cysts ≤ 20.0 mm), Category B (nodules ≥ 5.1 mm and/or cysts ≥ 20.1 mm), and Category C (requires immediate further examination). Participants classified as Categories B or C are recommended for secondary examination.

Results: Among 3398 participants with available ultrasound images obtained at the first health examination between January 2016 and October 2023, 45.2 % were classified as Category A1, 39.2 % as Category A2, 15.5 % as Category B, and 0 % as Category C. Of the 207 participants for whom secondary examination results were available, seven were diagnosed with cancer or suspected cancer.

Conclusions: An accuracy control system of thyroid ultrasonography has been established which will continue to carefully investigate the thyroids of Fukushima emergency workers.

On March 11, 2011, the Great East Japan Earthquake triggered the automatic shutdown of the Fukushima Daiichi Nuclear Power Plant of Tokyo Electric Power Company Holdings (TEPCO). The subsequent tsunami flooding caused a loss of backup power, leading to the meltdown of its 3 reactors and release of radioactive materials. The Japanese government responded to this accident by temporarily raising the emergency effective dose limit for workers from 100 mSv to 250 mSv between March 14, 2011 and December 16, 2011. During this critical period, approximately 20 000 individuals were involved in the emergency response work, with 174 individuals exposed to radiation exceeding the 100 mSv limit. In 2014, the Epidemiological Study of Health Effects in Fukushima Emergency Workers was initiated to monitor the long-term health effects of radiation on emergency workers. This prospective cohort study conducts regular health examinations to assess potential health consequences of radiation exposure.[1,2]

Consistent evidence indicates that radiation exposure in childhood increases the risk of developing thyroid cancer[3–6] and benign thyroid nodules.[7,8] However, the risk for thyroid cancer and nodules from radiation exposure decreases with increasing age at exposure,[9,10] and the evidence regarding risks in adulthood is inconsistent. While atomic bomb survivors exposed in adulthood have not shown an increased risk of thyroid cancer,[9–11] several studies suggested an elevated incidence or risk among Chernobyl cleanup workers.[12,13] Ron et al.[3] conducted a pooled analysis of thyroid cancer data from medically exposed individuals and atomic bomb survivors

and reported that the data on adult exposure was limited; therefore, the evidence of a radiation effect was insufficient.[3] This does not indicate a lack of a radiation effect, but rather, may suggest insufficient statistical power to detect a small effect. In response to the concerns of Fukushima emergency workers, Japanese government guidelines require emergency workers exposed to an effective dose ≥100 mSv to undergo periodic thyroid ultrasonography.[14]

In 2014, a thyroid study for Fukushima emergency workers was conducted using thyroid ultrasonography.[15] Six hundred and twenty-seven workers with estimated thyroid equivalent doses >100 mSv were classified as the exposure group and 1437 individuals as the control group. The findings showed that the prevalence of nodular thyroid lesions was not significantly associated with the preliminary estimated equivalent thyroid dose.

The current study expands the study cohort to include participants in the Epidemiological Study of Health Effects in Fukushima Emergency Workers in which thyroid ultrasonography is performed to investigate thyroid nodular lesions and cancer. The findings are expected to provide crucial insights into the effects of moderate- to low-dose radiation exposure (less than a few grays) on the thyroid during adulthood. This paper describes the thyroid study protocol and reports on the progress of the ultrasound examination at the first health examination through to October 2023.

Methods

Participants

A total of 19 812 emergency workers (19 787 males, 99.9 %) are included as eligible participants in the Epidemiological Study of Health Effects in Fukushima Emergency Workers. They have been invited to participate periodically in the Health Examination Study. The details of the study have been described elsewhere.[1,2] As emergency workers reside in various locations throughout Japan, more than 70 research partner institutions for health examinations (hereafter referred to as "health examination institutions") have been established nationwide. Participants are informed in advance about the health examination institutions available for thyroid ultrasonography and are permitted to choose where to undergo the health examinations. Participants who visit any of these institutions are asked for their consent to undergo ultrasonography after informing them of a possible benefit of early detection of thyroid cancer and a possible disadvantage of overdiagnosis of latent thyroid cancer.[16,17] Additionally, questions and concerns from participants before and after examinations are addressed.

Procedures of Thyroid Ultrasonography

Thyroid ultrasonography is performed at each health examination institution as 1 of the health examinations items. To ensure the accuracy of thyroid ultrasonography performed at multiple institutions, the Thyroid Accuracy Control (AC) Committee (NT, MM, and S. Yamamoto) was established at Jichi Medical University and conducts AC using 3 methods: 1) development of a standard procedure including an examination protocol, 2) training and certification of examiners, and 3) establishment of a central review system.

Standard procedure

The thyroid ultrasound device has a probe of frequency 7.5 MHz or higher, can store digital images, has color Doppler capability, and can store videos and transfer data to media. Certified examiners conduct examinations according to the standard procedures developed by the Thyroid AC Committee. This procedure details the steps for the preparation and execution of the examination according to the guidance of the Japan Association of Breast and Thyroid Sonology.[18] It also includes recording and transferring images for central review and the subsequent reception of central judgements, thus ensuring a uniform examination process. The examiner records the thyroid size, presence or absence of nodular lesions, and other findings. Thyroid nodular lesions are classified into 2 categories: solid nodule, hereafter referred to as "nodule," and cystic nodule, hereafter referred to as "cyst." In cases with nodules or cysts, the number, maximum diameter, and location of the largest lesions are recorded. When a solid component is present within a cyst, it is referred to as an intra-cystic nodule, and its maximum diameter is recorded. All images are digitally stored, and nodules suspected to be malignant are video-recorded.

Training and certification of examiners

The Thyroid AC committee regularly provides seminars for examiners at health examination institutions, including basic lectures and hands-on training in thyroid ultrasonography and lectures on thyroid diseases, cases, and reports of results. Examiners who are confirmed to have a certain level of knowledge, skill, and experience are registered as certified examiners, including those certified by the Japan Society of Ultrasonics in Medicine and the "Fukushima Health Management Survey."[19–21] Health examination institutions are registered as certified institutions if they have at least 1 certified examiner who has attended a designated seminar. As of October 2023, 153 certified examiners and 65 certified institutions were involved in this study.

Central review system

A Central Review System was established for thyroid ultrasonography (Figure 1). In the system, images and results obtained at health examination institutions are electronically transferred to the database of the headquarters (National Institute of Occupational Safety and Health, Japan), and the ultrasound experts (NT and/or S. Yamamoto) at the Thyroid AC Committee access the database to review and judge them. The reports of the central judgement are transferred to each health examination institution through the system and sent to the participants. This system has been fully operational since April 2017, and since then, the images of all participants have been centrally reviewed.

Thyroid Ultrasound Categories

Thyroid nodular lesions are classified into categories A (A1 and A2), B, or C using a modified classification of the Fukushima Health Management Survey.[19,21] Category A indicates that no further examination is required and is further classified into subcategories A1 and A2. Category A1 indicates the absence of both nodules and cysts, and Category A2 indicates the presence of nodules with a maximum diameter ≤ 5.0 mm and/or cysts with a maximum diameter ≤ 20.0 mm. Category B and Category C indicate that further examination is required. Category B indicates the presence of nodules with a maximum diameter ≥ 5.1 mm and/or cysts with a maximum diameter ≥ 20.1 mm. Intra-cystic nodules are considered nodules and are classified as Category A2 if the maximum diameter is ≤ 5.0 mm and Category B if the maximum diameter is ≥ 5.1 mm. Category C indicates the presence of findings that require immediate further examination.

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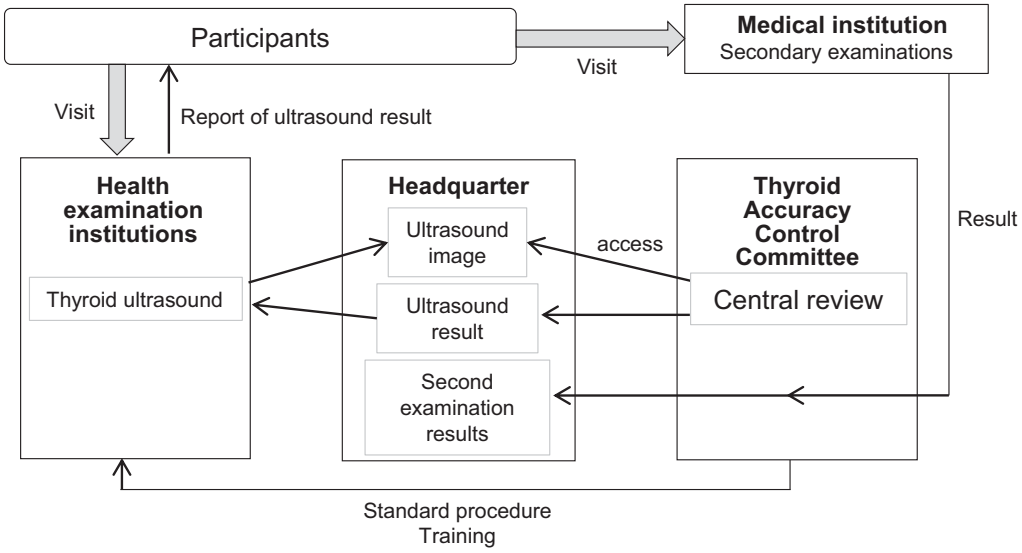

Figure 1. Central review system of thyroid ultrasonography.
US: ultrasonography.
The headquarters and thyroid accuracy control committee are located at the National Institute of Occupational Safety and Health, Japan and Jichi Medical University, respectively. Between 2016 and 2023, 65 health examination institutions and 133 medical institutions conducting secondary examinations were involved in the study.

Secondary Examination

Medical institutions with thyroid experts were requested to become cooperative institutions that accept secondary examinations. A total of 133 medical institutions had agreed by October 2023. Participants categorized as B or C receive a referral letter to a medical institution recommending a secondary examination. In the secondary examination, ultrasonography is re-examined, and fine-needle aspiration cytology, blood tests, and other examinations are performed, if necessary. The results are sent to the Thyroid AC committee and electronically transferred to the headquarters database and confirmed by thyroid experts (MI and MM) (Figure 1).

Radiation Dose

The tentative estimated effective doses (mSv) during emergency operations for each worker were obtained by combining the external and internal exposure doses registered as tentative doses in the database of the Ministry of Health, Labour, and Welfare of the Japanese government (MHWL). The details are described elsewhere.[2] The thyroid equivalent and absorbed doses for individuals are evaluated using data provided by the MHWL and TEPCO, as described elsewhere.[1]

Ethical Issues

This study was approved by the Institutional Review Board of the National Institute of Occupational Safety and Health, Osaka University, Jichi Medical University, and the Radiation Effects Research Foundation. Written informed consent is obtained from all the participants.

Study Progress

Herein, the progress of thyroid ultrasonography at the first health examination by October 2023 is reported. As shown in Figure 2, 6355 participants (32.1% of the 19 787 eligible emergency workers) agreed to undergo their first health examination between January 2016 and October 2023. Of the 4887 participants who visited an institution available for thyroid ultrasonography and who agreed to be examined, 4736 participants underwent thyroid

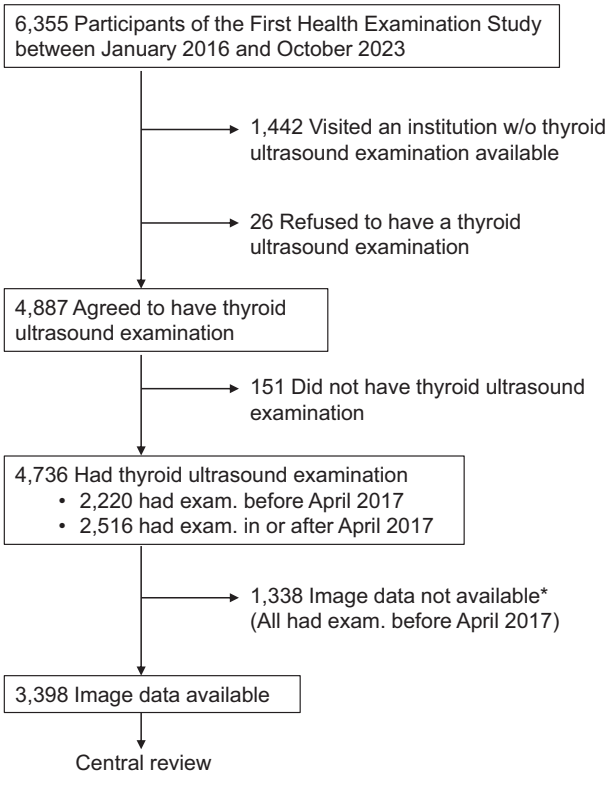

Figure 2. Participants and availability of images of thyroid ultrasonography.
US: ultrasonography.
*The central system of images has been fully operational since April 2017 and images of all participants have been transferred from health examination institutions for the study and centrally reviewed. Prior to that, from January 2016-March 2017, images of most participants (1338 of 2220 participants) were reviewed and stored only at individual health examination institutions and were not available for the study.

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ultrasonography, and the images of 3398 participants were available (71.7 % of the 4736 participants who underwent examination and 53.5 % of the total 6355 participants). As the central review system was not fully operational before April 2017, images of 1338 of the 2220 participants who were examined prior to that time, from January 2016 to March 2017, were reviewed and stored at individual health examination institutions and were not available for the study. Supplemental Table 1 shows number of eligible emergency workers, participants of the Health Examination Study, those who underwent ultrasound examinations, and those with available image data, categorized by estimated effective doses. Among the eligible emergency workers, 30.0%-33.4% of those with an effective dose of less than 50 mSv participated in the Health Examination Study, whereas 42.8%-62.3% of those with an effective dose of 50 mSv or higher participated. Among the participants in the Health Examination Study, image data were available for 48.2%-61.0% of those with an effective dose of less than 50 mSv, whereas image data were available for 71.0% to 74.3% of those with an effective dose of 50 mSv or higher.

Table 1 presents the characteristics of the participants. Almost all participants (99.7 %) were male and the mean ± standard deviation (SD) age at the time of accident on March 11, 2011, was 44.2 ± 10.6 years. The estimated tentative effective dose during emergency work ranged from 0-645.5 mSv with a mean of 18.2 mSv and median of 7.2 mSv. Individual thyroid radiation doses were unavailable due to estimation work in progress. The mean ± SD age at the time of examination was 51.4 ± 10.7 years. Most participants (72.0 %) were examined in 2017 or 2018, 6 or 7 years after the accident.

Table 2 shows the criteria for the thyroid ultrasound categories, and the number and percentage of participants in each category at the first health examination. Overall, 84.4 % of the participants were classified as Category A, which required no further examination, consisting of 45.2 % A1 and 39.2 % A2. Another 15.5 % were classified as Category B, requiring further examination. No participants were judged as Category C, and 2 were not categorized because of insufficient image quality.

Table 3 and Figure 3 show the number and percentage of participants in each thyroid category, classified by age at examination, and the estimated tentative effective dose. As shown in Figure 3A, the percentages of participants in Category A (A1 or A2) were 96.6%, 93.6 %, 87.9 %, 82.4 %, 78.7 %, and 68.5 % in age groups 20-29 years, 30-39 years, 40-49 years, 50-59 years, 60-69 years, and 70-79 years, respectively. The percentages of participants in Category B were 1.1 %, 6.4 %, 12.1 %, 17.6 %, 21.3 %, and 31.5 % in age groups 20-29 years, 30-39 years, 40-49 years, 50-59 years, 60-69 years, and 70-79 years, respectively. In contrast, as shown in Figure 3B, the percentages of participants in Category A (A1 or A2) were 84.2 %, 85.5 %, 84.4 %, 82.8 %, 86.2 %, and 84.6 % in the <5 mSv, 5-9.99 mSv, 10-19.99 mSv, 20-49.99 mSv, 50-99.99 mSv, and >=100 mSv dose groups, respectively. The percentages of participants in Category B were 15.7 %, 14.5 %, 15.6 %, 17.0 %, 13.8 %, and 15.4 % in the <5 mSv, 5-9.99 mSv, 10-19.99 mSv, 20-49.99 mSv, 50-99.99 mSv, and >=100 mSv dose groups, respectively.

Participants whose thyroids were categorized as Category B were advised to visit a cooperating medical institution for secondary examination. As of October 2023, the Thyroid AC Committee received the results of secondary examinations from 207 participants (39.2 %). Of these, 7 participants were diagnosed with or suspected of having thyroid malignancy, but none of them received a high effective dose of >100 mSv during emergency work.

Table 1. Characteristics of participants with available images

	Number (%)
Participants with central review	3398
Male	3387 (99.7)
Age at accident, years	
Mean, SD	44.2, 10.6
<20	24 (0.7)
20–29	328 (9.7)
30–39	769 (22.6)
40–49	1088 (32.0)
50–59	984 (29.0)
60–69	203 (6.0)
70–79	2 (0.1)
Estimated tentative effective dose during emergency works, mSv	
Mean, SD	18.2, 29.9
Median, range	7.2, 0 – 645.5
< 5	1458 (42.9)
5–9.99	454 (13.4)
10–19.99	525 (15.5)
20–49.99	547 (16.1)
50–99.99	275 (8.1)
≥ 100	78 (2.3)
Unknown	61 (1.8)
Age at examination, years	
Mean, SD	51.4, 10.7
< 20	0
20–29	88 (2.6)
30–39	409 (12.0)
40–49	947 (27.9)
50–59	1079 (31.8)
60–69	783 (23.0)
70–79	92 (2.7)
Calendar year at the first examination	
2016	134 (3.9)
2017	1426 (42.0)
2018	1018 (30.0)
2019	362 (10.7)
2020	149 (4.4)
2021	74 (2.2)
2022	148 (4.4)
2023	87 (2.6)

Parentheses indicate percentages of 3398 participants. SD: Standard deviation.

Limitations

This study currently has several limitations. First, it was not possible to assess radiation risk due to the unavailability of thyroid

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Table 2. Criteria of thyroid ultrasound categories and number of participants by the thyroid categories

Thyroid category		Criteria	Number (%)
A	A1	Absence of both nodules and cysts	1,535 (45.2)
	A2	Presence of nodules with a maximum diameter ≤ 5.0 mm and/or cysts with a maximum diameter ≤ 20.0 mm	1,333 (39.2)
B		Presence of nodules with a maximum diameter ≥ 5.1 mm and/or cysts with a maximum diameter ≥ 20.1 mm	528 (15.5)
C		Presence of findings that require immediate further examinations	0
Not done (ND)		Judgement is not done due to insufficient quality of images	2 (0.1)
Total			3,398 (100)

Intra-cystic nodules are considered nodules and are classified as Category A2 if maximum diameter ≤ 5.0 mm and Category B if maximum diameter ≥ 5.1 mm.
Secondary examination is recommended for participants who are judged as B or C for detailed examinations.
Parentheses indicate percentages of 3398 participants.

Table 3. Number of participants by the thyroid ultrasound categories by sex, age at examination, and effective dose during emergency work

	Thyroid category					
	A1	A2	B	C	NA	Total
Sex						
Male	1530	1330	525	0	2	3387
Female	5	3	3	0	0	11
Age at examination, years						
20–29	52	33	1	0	2	88
30–39	229	154	26	0	0	409
40–49	492	340	115	0	0	947
50–59	450	439	190	0	0	1079
60–69	278	338	167	0	0	783
70–79	34	29	29	0	0	92
Estimated effective dose during emergency works, mSv						
< 5	645	583	229	0	1	1458
5–9.99	219	169	66	0	0	454
10–19.99	247	196	82	0	0	525
20–49.99	238	215	93	0	1	547
50–99.99	122	115	38	0	0	275
≥100	32	34	12	0	0	78
Unknown	32	21	8	0	0	61
Total	1,535	1,333	528	0	2	3398

NA: Not Available due to insufficient quality of images.

radiation dose data and there was insufficient outcome data, as secondary examination data was obtained for only 39.2 % of participants who were identified as requiring further examination. However, individual thyroid dose estimation is ongoing, and additional secondary examination data is being collected. The analysis will be performed once the necessary information becomes available. Second, it is highly probable that certain thyroid nodular lesions and cancers identified during the first health examination existed before the emergency work. Therefore, a longitudinal analysis of their incidence is necessary. Third, selection bias may have existed among the participants; details of this potential bias are discussed in the following section.

Discussion

In the Health Examination Study of Fukushima emergency workers, a system was established to control the accuracy of thyroid ultrasonography performed at more than 60 institutions. In the first health examination between 2016 and 2023, 15.5 % of participants had thyroid nodular lesions requiring secondary examination, and 7 cases were diagnosed with cancer or suspected cancer.

The strength of this study is that thyroid ultrasonography of Fukushima emergency workers is performed with high accuracy, and thyroid nodules, cysts, and cancers are systematically identified. Thyroid ultrasonography generally has inter-observer variation.[22,23] The accuracy of ultrasonography is controlled by creating a standard procedure using a unified protocol, continuous training of examiners, and central review and judgement by experts. Clear criteria were also defined for referrals for secondary examination. These efforts are important for ensuring the reliability of this study.

Thyroid nodular lesions are common in the general population, identified in 19%-68% by thyroid ultrasonography, and their prevalence increases with age and progress of technology.[24,25] In the first health examination of this study, nodular lesions were identified in 54.7 % of the participants (39.2 % in Category A2 and 15.5 % in Category B), and the percentage of Category B cases increased with age, which appears to reflect the trend observed in the general population. In contrast, the percentage of participants in each thyroid ultrasound category was similar in all tentative effective dose groups. Studies on atomic bomb survivors and children exposed to the Chernobyl accident reported a significant association between the prevalence of nodules and thyroid radiation dose, with the risk decreasing with increasing age at the time of exposure.[7,10,26] In this study, the radiation effect should not be interpreted at this time because individual thyroid radiation doses were unavailable. Thyroid radiation doses are affected by internal exposure to radioiodine and prophylactic administration of stable iodine. Furthermore, the radiation dose is affected, not only by the exposure dose during emergency work, but also the cumulative dose from usual operations in a nuclear power plant and medical radiation. The estimation of the individual thyroid dose is essential in the risk analysis of radiation exposure.

According to the National Cancer Registry survey, the annual incidence of thyroid cancer in Japanese males is 8.0 per 100 000 males.[27] Kamo et al.[28] also reported that the probability of a Japanese male developing thyroid cancer during his lifetime is estimated to be 0.23 % in an analysis based on cancer registry incidence data from 1975 to 1999.[28] On other hand, it is well known that there are latent thyroid cancers that have no lifelong symptoms and are not life-threatening. The frequencies of thyroid cancer detected by thyroid ultrasound screening in the general adult population have been reported to be 0.12-0.53 % in males.[29] Furthermore, the autopsy detection of latent cancer was reported to be 28.4 % in Japan[30] and 35.4 % in Finland.[31] As Fukushima emergency workers are more likely to undergo ultrasound screening than the general population, an elevated incidence of thyroid cancer,

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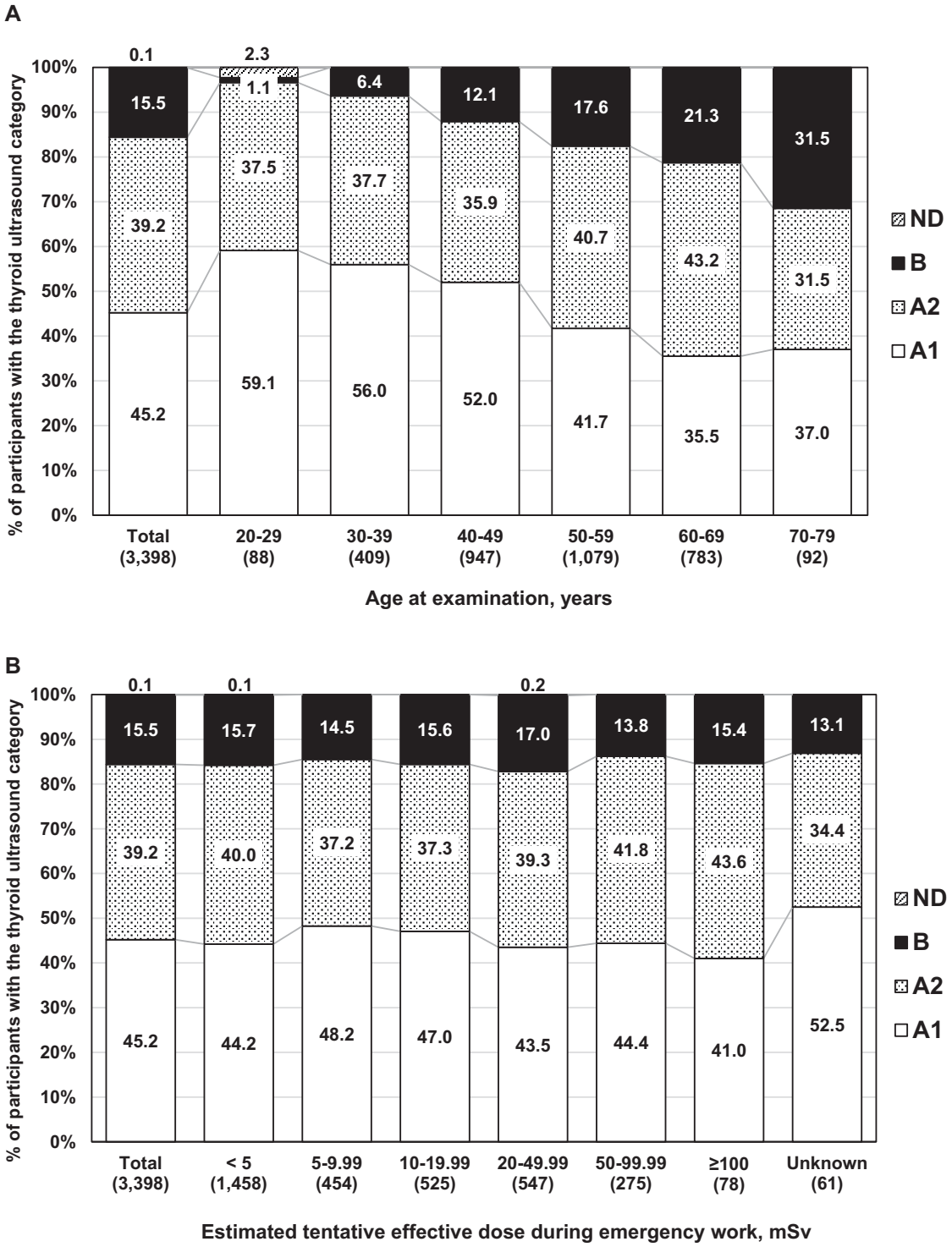

Figure 3. Percentage of participants in each thyroid ultrasound category.
US: ultrasonography; ND: classification was not performed because of insufficient image quality.
The percentage of participants in each thyroid ultrasound category was classified by age at the time of examination (A) and the estimated tentative effective dose during emergency work (B). Parentheses on the x-axis indicate the number of participants in each age and dose group. The numbers in the bars indicate the percentages of participants in each thyroid ultrasound category.

including latent cases, is anticipated. Therefore, directly comparing cancer incidence with cancer registry data from the general population is not appropriate. While the high risk of thyroid cancer due to childhood radiation exposure is well known,[3–6] evidence regarding the risk associated with adult exposure remains inconsistent. A meta-analysis examining thyroid cancer risk by adult radiation exposure found a higher standardized incidence ratio but no increase in relative risk with increasing dose.[32] Work is currently continuing to collect additional outcome information. To better understand thyroid cancer in Fukushima emergency workers, it will be crucial

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to consider the potential for latent cancers by evaluating detailed case information, such as tumor size and extent.

A possible selection bias may have existed in this study because more participants individuals in the high-dose group participated in the Health Examination Study and visited a health examination institution where thyroid ultrasonography was available (supplemental Table 1). As participants were permitted to choose a health examination institution, those exposed to high doses of radiation may have been more concerned about their thyroids, which may have motivated them to undergo ultrasonography. Furthermore, those with a history of thyroid nodular lesions detected prior to this study or a family history of thyroid disease might have also been influenced in their motivation, leading to selection bias. This selection bias can also occur in accessing secondary examinations, as well as in the participation in the Health Examination Study, as described elsewhere.[2] Furthermore, data of approximately 30% of participants who underwent ultrasonography were unavailable in the first health examination because the Central Review System was under construction in the early phase of the study. Medical history, family history, and examination time will be examined to account for the possibility of bias in a risk analysis. In addition, the criteria for recommending aspiration biopsy for secondary examinations may vary among clinicians. However, it is assumed that all clinicians, as thyroid-disease experts, would align with the guidelines established by academic societies.[18,25,33] Considering these limitations, multifaceted studies using different approaches, such as cancer registry information or medical histories, in addition to this study using ultrasound screening, are warranted.

Conclusions

A system to control the accuracy of thyroid ultrasonography for Fukushima emergency workers has been established. The results of the thyroid screening cannot be directly compared with the prevalence or incidence of thyroid disorders in the general population due to differences in case identification methods and study population characteristics. Soon, upon the availability of thyroid radiation doses and detailed case information, we will employ these data for risk assessments.

Supplementary material. The supplementary material for this article can be found at http://doi.org/10.1017/dmp.2025.103.

Author contribution. Imaizumi: Design, analysis and interpretation of data, and drafting; Sobue and Okubo: Conception, design, interpretation of data, and revision; Taniguchi and Miyakawa: Design, acquisition and interpretation of data, and revision; Momose, Yoshinaga, Ohishi, and Kitamura: Design, interpretation of data, and revision; Yamamoto: Acquisition and interpretation of data, and revision; Zha: Design, analysis and interpretation of data, and revision.

All authors approved the final version of the manuscript.

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Competing interests. None.

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