Original Paper

Prevalence of Insomnia Among Residents of Tokyo and Osaka After the Great East Japan Earthquake: A Prospective Study

Hiroaki Sugiura[1*], MD, PhD; Manabu Akahane[1*], MD, PhD; Yasushi Ohkusa[2*], PhD; Nobuhiko Okabe[2*], MD, PhD; Tomomi Sano[1*], MD, PhD; Noriko Jojima[3*], MSN; Harumi Bando[3*], MS; Tomoaki Imamura[1*], MD, PhD

[1]Health Management and Policy, Department of Public Health, Nara Medical University School of Medicine, Kashihara, Japan

[2]National Institute of Infectious Diseases, Infectious Disease Surveillance Center, Tokyo, Japan

[3]Faculty of Nursing, Nara Medical University School of Medicine, Kashihara, Japan

[*]all authors contributed equally

Corresponding Author:
Hiroaki Sugiura, MD, PhD
Health Management and Policy
Department of Public Health
Nara Medical University School of Medicine
840 Shijo-cho
Kashihara, 634-8521
Japan
Phone: 81 744 22 3051 ext 2224
Fax: 81 744 25 7657
Email: tomomarie@smn.enjoy.ne.jp

Abstract

Background: The Great East Japan Earthquake occurred on March 11, 2011. Tokyo and Osaka, which are located 375 km and 750 km, respectively, from the epicenter, experienced tremors of 5.0 lower and 3.0 seismic intensity on the Japan Meteorological Agency scale. The Great East Japan Earthquake was the fourth largest earthquake in the world and was accompanied by a radioactive leak at a nuclear power plant and a tsunami. In the aftermath of a disaster, some affected individuals presented to mental health facilities with acute stress disorder (ASD) and/or post-traumatic stress disorder (PTSD). However, few studies have addressed mental stress problems other than ASD or PTSD among the general public immediately after a disaster. Further, the effects of such a disaster on residents living at considerable distances from the most severely affected area have not been examined.

Objective: This study aimed to prospectively analyze the effect of a major earthquake on the prevalence of insomnia among residents of Tokyo and Osaka.

Methods: A prospective online questionnaire study was conducted in Tokyo and Osaka from January 20 to April 30, 2011. An Internet-based questionnaire, intended to be completed daily for a period of 101 days, was used to collect the data. All of the study participants lived in Tokyo or Osaka and were Consumers' Co-operative Union (CO-OP) members who used an Internet-based food-ordering system. The presence or absence of insomnia was determined before and after the earthquake. These data were compared after stratification for the region and participants' age. Multivariate analyses were conducted using logistic regression and a generalized estimating equation. This study was conducted with the assistance of the Japanese CO-OP.

Results: The prevalence of insomnia among adults and minors in Tokyo and adults in Osaka increased significantly after the earthquake. No such increase was observed among minors in Osaka. The overall adjusted odds ratios for the risk of insomnia post-earthquake versus pre-earthquake were 1.998 (95% CI 1.571–2.542) for Tokyo, 1.558 (95% CI 1.106–2.196) for Osaka, and 1.842 (95% CI,1.514–2.242) for both areas combined.

Conclusions: The prevalence of insomnia increased even in regions that were at a considerable distance from the epicenter. Both adults and minors in Tokyo, where the seismic intensity was greater, experienced stress after the earthquake. In Osaka, where the earthquake impact was milder, disturbing video images may have exacerbated insomnia among adults.

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KEYWORDS

insomnia; Web-based survey; population surveillance; disaster; nuclear accidents; earthquakes

Introduction

On March 11, 2011, the Japanese islands sustained a 9.0-magnitude earthquake. Unlike previous major earthquakes in Japan [1,2], this earthquake was followed by a tsunami that devastated the affected areas [3]. More than 20,000 individuals were recorded as dead or missing. The tsunami also caused extensive damage to the Fukushima Daiichi nuclear power plant, resulting in a level 7 nuclear accident [4,5]. This induced considerable anxiety among residents living near the nuclear power plant and among people living as far away as the Tokyo metropolitan area [6]. Images of the tsunami and scenes of the nuclear accident were shown repeatedly on television and the Internet.

In the aftermath of a disaster, people may experience not only physical disorders but also acute stress disorder (ASD), which can persist for up to 4 weeks. Furthermore, chronic post-traumatic stress disorder (PTSD) is common among individuals who have faced such situations [7]. Studies of disaster-related mental disorders typically include an assessment of the prevalence of PTSD, follow-up of patients diagnosed with ASD [8], and a comparison of the numbers of new and previous cases of PTSD in a given area. However, because these studies are usually planned after a disaster, pre-disaster prevalence must be determined retrospectively. A recollection of previous insomnia is likely to be less accurate than the prospective reporting of current symptoms of insomnia, especially during the traumatic aftermath of a disaster.

The current study made use of a daily health survey that was administered to 3128 participants in Tokyo and 1925 participants in Osaka (Table 1) from January 20 to April 30, 2011. One question on the survey specifically asked about the presence or absence of insomnia. Because the Great East Japan Earthquake occurred during the course of this survey, this was a rare opportunity to prospectively assess the impact of an earthquake on the prevalence of insomnia among residents of Tokyo and Osaka.

Table 1. Number of participants according to sex and age group.

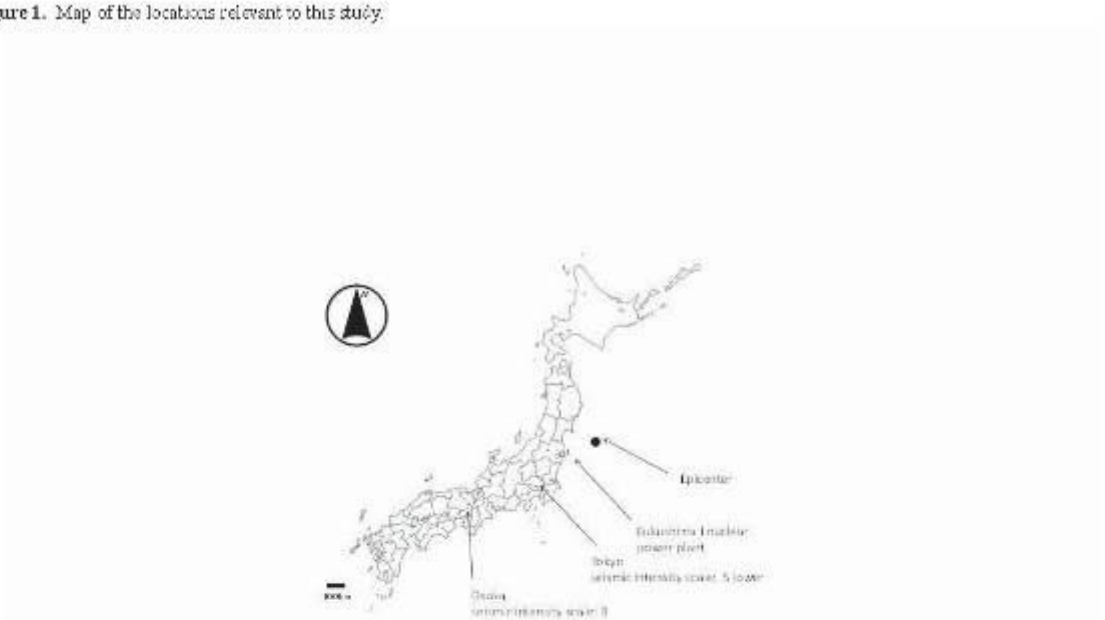
	Tokyo N (male/female)	Osaka N (male/female)
Adults (≥20 years of age)	2073 (999/1074)	1182 (564/618)
Minors (<20 years of age)	1055 (575/480)	743 (373/370)

Methods

Study Period and Locations

This survey began on January 20, 2011 and continued for 101 days until April 30, 2011. The questionnaire collected data related to the individual's health status on the day of the survey, and participants were instructed to complete the survey every day for the duration of the study period. The survey was conducted via an Internet-based questionnaire among residents of the Tokyo metropolitan area and Osaka, the largest city in western Japan. Tokyo is located approximately 375 km from the epicenter of the earthquake (N 38°06′ E 142°51′) and approximately 200 km from the Fukushima Daiichi nuclear power plant (N 37°42′ E 141°03′). The seismic intensity of the main shock in the center of Tokyo, as recorded by the Japan Meteorological Agency (JMA), was 5.0 Lower on the JMA scale [9]. The JMA scale is comprised of 5 phases from 1 to 5. Grades 5 and 6 are further classified into 2 subcategories: upper and lower. During an earthquake with an intensity of 5.0 Lower, people may find it difficult to move around, but major destruction is generally not expected. In contrast, many people find it hard to move during earthquakes with an intensity of 5.0 Upper [9]. Shinjuku Ward, where the offices of the Tokyo Metropolitan Government are located, was subsequently hit by 10 aftershocks that continued until April 16, 2011. The seismic intensity of the aftershocks was ≥3.0, strong enough to be felt by most people inside buildings [9]. Osaka, the other area investigated in the survey, is situated 750 km from the epicenter of the earthquake. The seismic intensity of the main shock was recorded as 3.0 in the offices of the Osaka Prefectural Government. Osaka did not receive any aftershocks with a seismic intensity ≥3.0 (Figure 1).

Figure 1. Map of the locations relevant to this study.



Participants

This study was conducted with the assistance of the Japanese Consumers' Co-operative Union (CO-OP). All respondents who completed the questionnaire lived in Tokyo or Osaka and resided in households that included CO-OP members who placed food orders via the CO-OP website.

Survey Method

This study was conducted with the approval of the Ethics Committee of Nara Medical University (authorization code: 220). The general health condition of the participants, including their sleeping patterns, was investigated using an Internet-based questionnaire. The original aims of this survey were to determine the impact of biological factors, such as infectious diseases, and abiotic factors, such as climate, on the physical condition of residents during the study period. The survey method and data processing methods were described in detail in our previous study [10].

Registration Method

Respondents were recruited through a banner advertisement on the CO-OP's website. Each participant was rewarded with 500 yen (US $1=91.15 yen on the first day of the survey) upon registration for participating in the survey. No remuneration, in the form of cash, was given for providing answers on a daily basis.

Daily Survey Method

The original research plan was to send a reminder email to all the respondents on each day of the survey that would direct them to the website where they could provide their responses. The email was distributed as planned until day 50 of the survey. The Great East Japan Earthquake occurred on day 51 of the survey. The reminder emails were discontinued, as it was decided that the participants, who were recovering from the disaster, should not be burdened. Further responses were left to the participants' discretion during a hiatus period from March 14 to April 5, 2011, when the reminders were reinstituted. After the earthquake, respondents were able to submit descriptions of their physical condition by voluntarily visiting the website.

The daily survey procedure was designed to be simple. After confirming the everyday health condition of the family, participants were asked to access the survey website and answer several questions. The first question asked whether any family member was in poor health. If the participant answered "no", they were excluded from the survey. If the participant answered "yes", they were asked to answer additional "yes" or "no" questions on 19 symptoms; these questions pertained to the individual filling out the questionnaire as well as each member of his or her family [10]. The presence or absence of insomnia was prospectively investigated for 50 days before and 51 days after the Great East Japan Earthquake (including the day of the earthquake).

Statistical Analysis

In both surveyed areas, the prevalence of insomnia was calculated on a daily basis (the number of people reporting symptoms of insomnia divided by the number of responses per day) among people aged <20 years and those aged ≥20 years. Using a chi-square test, the presence or absence of insomnia before and after the earthquake was investigated for any correlation with region or participant age. A multivariate analysis was carried out using logistic regression analysis and a generalized estimating equation. The presence or absence of insomnia was the dependent variable. The independent variables included insomnia occurring after the earthquake, sex, age, region of each participant, the status of reminder emails (sent or not), and the incidence of pollinosis, which plagued approximately 30% of adults in those urban areas during the spring [11]. The statistical analyses were carried out using SPSS version 19.0 (IBM, Chicago, IL, USA).

Results

Response Rate

The mean (SD) daily response rate during the period when reminder emails were sent was 64.17% (5.78%) for Tokyo and 68.31% (5.18%) for Osaka. The response rate did not decline significantly over the course of the study. The response rate during the period when no reminder emails were sent (March 14 to April 5, 2011) was 24.47% (12.97%) for Tokyo and 27.82% (13.55%) for Osaka.

Daily Prevalence of Insomnia

Figures 2 and 3 illustrate the daily prevalence of insomnia in Tokyo and Osaka, respectively, according to age. The figures also indicate the dates of the main earthquake and the aftershocks with seismic intensity ≥3.0. Before the earthquake, the average daily prevalence of insomnia in Tokyo was 1.05% (0.18%) for adults (age ≥20 years) and 0.53% (0.22%) for minors (age <20 years); after the earthquake, this value increased to 2.35% (0.65%) for adults and 1.90% (1.17%) for minors. The maximum seismic intensity of the main earthquake was 5.0 Lower in Tokyo (Figure 2).

Before the earthquake, the average daily prevalence of insomnia in Osaka was 1.25% (0.25%) for adults and 0.092% (0.14%) for minors; after the earthquake, this value increased to 1.83% (0.51%) for adults but remained approximately the same at 0.089% (0.17%) for minors. The maximum seismic intensity of the main earthquake was 3.0 in Osaka (Figure 3).

A chi-square test was conducted to analyze the data according to region and age group. There was a significant increase in the number Tokyo residents who reported symptoms of insomnia after the earthquake ($P<.001$ for both adults and minors) compared with that before the earthquake. The same findings were reported for adults in Osaka after the earthquake ($P<.001$). No significant difference was observed among minors in Osaka (Table 2). We conducted a similar chi-square test that excluded the period during which no reminder emails were sent and similar results were obtained.

Table 2. Chi-square analysis according to sex and age.

Region		Chi-square value	Degrees of freedom	*P*	Odds ratio	95% CI
Tokyo	Adults	246.63	1	<.001	2.107	1.916–2.317
	Minors	128.52	1	<.001	2.763	2.301–3.319
Osaka	Adults	34.65	1	<.001	1.438	1.273–1.623
	Minors	0.087	1	.77	1.096	0.595–2.020

Figure 2. Prevalence of insomnia in Tokyo. The prevalence of insomnia increased after the earthquake for both adults and minors in Tokyo.

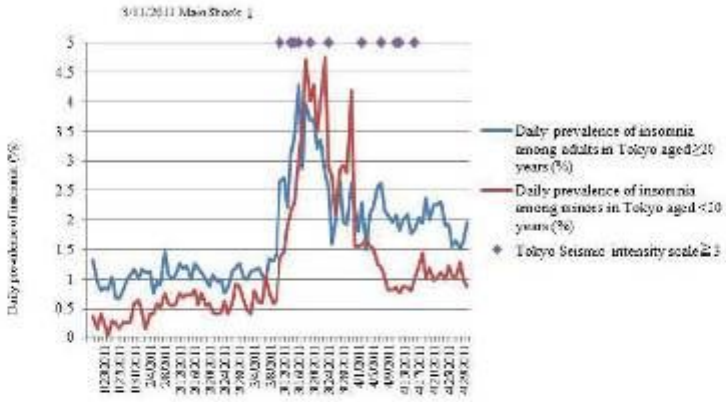
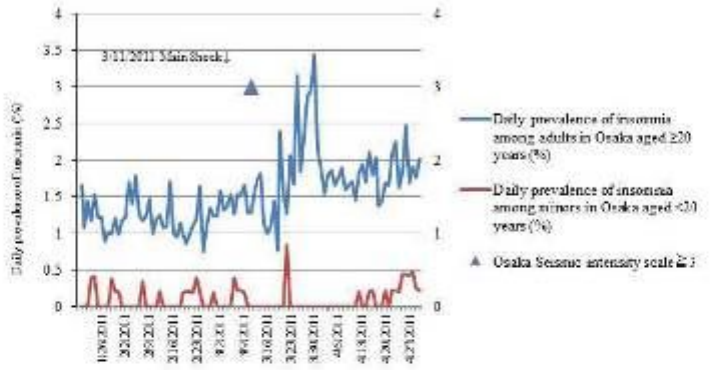


Figure 3. Prevalence of insomnia in Osaka. The prevalence of insomnia among adults increased after the earthquake. The prevalence of insomnia among minors remained approximately the same as that before the earthquake.



Analysis of Factors Associated with the Prevalence of Insomnia

Multivariate analysis was conducted to determine the odds ratios for insomnia (Table 3). The adjusted odds ratios for insomnia after versus before the earthquake were 1.998 (95% CI 1.571–2.542, $P<.001$) for Tokyo, 1.558 (95% CI 1.106–2.196, $P=.011$) for Osaka, and 1.842 (95% CI1.514–2.242, $P<.001$) for the 2 areas combined. Table 3 presents the factors analyzed in this study and their associations with the prevalence of insomnia.

Table 3. Multivariate analysis of factors associated with the prevalence of insomnia.

	Odds ratio	*P*	95% CI
Predictor for sleeplessness [a]			
Post-earthquake vs pre-earthquake	1.842	<.001	1.514–2.242
Age ≥20 years vs age <20 years	2.246	.027	1.095–4.605
Female vs male	1.510	.109	0.912–2.501
Presence vs absence of pollinosis	2.334	.001	1.437–3.791
Tokyo vs. Osaka	1.404	.187	0.848–2.323
No reminder email vs reminder email	1.303	.016	1.050–1.617
Predictor of sleeplessness			
Tokyo			
Post-earthquake vs pre-earthquake	1.998	<.001	1.571–2.542
Age ≥20 years vs age <20 years	1.378	.421	0.631–3.010
Female vs male	1.670	.903	0.90–3.087
Presence vs absence of pollinosis	2.437	.005	1.317–4.509
No reminder email vs reminder email	1.435	.004	1.121–1.838
Osaka			
Post-earthquake vs pre-earthquake	1.558	.011	1.106–2.196
Age ≥20 years vs age <20 years	13.987	<.001	6.408–30.530
Female vs male	1.285	.554	0.554–2.983
Presence vs absence of pollinosis	2.193	.047	1.012–4.751
No reminder email vs reminder email	1.005	.983	0.658–1.535

[a] values are total counts from Tokyo and Osaka

Discussion

Overall

This study examined the prevalence of insomnia among residents in areas that were at different distances from the epicenter of the Great East Japan Earthquake. This is a unique study in that it analyzes the effect of a great earthquake on the rates of insomnia and includes a pre-event baseline in the same group.

Great East Japan Earthquake and Its Impact

Major earthquakes have been common throughout the Asia-Pacific region over the past 2 decades [12,13], with more major earthquakes occurring in Japan than in any other country. In recent decades, 4 particularly large earthquakes have hit Japan, including the Great Hanshin Earthquake of 1995, which hit the Osaka region [1,2,14,15]. The Great East Japan Earthquake was the fourth largest earthquake in the world and was accompanied by 2 major events that could have occurred only in a modern society. First, the earthquake caused a radioactive leak at a nuclear power plant. Second, video images of the ensuing tsunami were recorded, and the footage was shown repeatedly on television; they were also available on the Internet. These images had a profound psychological impact on viewers. In the aftermath of a disaster, affected individuals may present to mental health facilities with ASD and/or PTSD [16-19]. However, few studies have addressed mental stress problems other than ASD or PTSD among the general public immediately after a disaster. Although ASD and PTSD tend to draw greater research attention in studies related to a major disaster, the effects of such a disaster on residents living at considerable distances from the most severely affected area have not been examined. This study revealed an increase in the prevalence of insomnia among the general public immediately after the occurrence of a major earthquake. To our knowledge, this is the first study conducted in Japan that presents longitudinal data on the persistence of insomnia in 2 age groups.

Daily Prevalence of Insomnia in Tokyo and Osaka

The daily prevalence of insomnia increased among both adults and minors in Tokyo after the Great East Japan Earthquake. Although the daily prevalence of insomnia increased among adults in Osaka, a similar increase was not observed among minors. The adjusted odds ratios for insomnia after versus before the earthquake were 1.998 (95% CI 1.571–2.542) for Tokyo, 1.558 (95% CI 1.106–2.196) for Osaka, and 1.842 (95% CI 1.514–2.242) for the 2 areas combined. These results demonstrate an increased prevalence of insomnia among residents in regions located at considerable distances from the immediate zone of the disaster. In Tokyo, where there was no observable infrastructure damage due to the tsunami, 7 people died as a result of the initial tremor. In addition, many people in Tokyo experienced considerable psychological strain for a

prolonged period. Many commuters were stranded because of interrupted transportation services, and there was a high risk of radioactive contamination associated with the nuclear accident. The increased prevalence of insomnia among minors in Tokyo, who are generally less susceptible to stress induced by indirect sources such as media coverage, may be attributable to the effects of the aftershocks. In contrast, the seismic intensity of the main shock in Osaka was 3.0; therefore, direct feelings of fear were likely to be less common, and there was an absence of palpable aftershocks. The prevalence of insomnia among minors in Osaka following the earthquake was not increased, which can be explained by the residents' exposure to fewer direct and local effects. However, an increased number of adults in Osaka reported insomnia. This may have stemmed from exposure to information reported by the media. Other possible causes of insomnia among these adults include anxiety about their future and memories of the disaster caused by the Great Hanshin Earthquake of 1995.

Questionnaire Survey and Its Advantages

A Web-based questionnaire survey was used in the current study because more data are acquired with Internet-based epidemiological surveys than with conventional, paper-based surveys [20,21]. This method was effective in targeting general residents and enabling the acquisition of information from people with medical complaints deemed very mild to warrant a visit to a medical facility. In addition, this survey method was successful because the participants were required to respond only to simple questions regarding the presence or absence of symptoms, thus, the input burden was low. Although a meta-analysis of 68 studies [22] indicated that the normal response rate to Internet-based surveys is low (39.6%), the daily response rate for this study during the period when reminder emails were sent was 64.17% (5.78%) for Tokyo and 68.31% (5.18%) for Osaka. The survey questions were not specifically designed to detect post-disaster psychological conditions, and insomnia was only 1 of several conditions investigated. Participants' responses were limited to the presence or absence of insomnia, and there was no attempt to determine the severity of the condition. Because insomnia was investigated as only 1 of several conditions, participants were unaware that their responses would be used in a study on post-disaster stress, even after the earthquake struck. It is possible, therefore, that the participants were less inclined to answer "yes" to the question about any experience of insomnia symptoms. This possibility is supported by the fact that the average daily prevalence of insomnia among adults before the earthquake was 1.1% in Tokyo and 1.3% in Osaka; these rates are lower than the values reported by an earlier survey on the prevalence of insomnia among Japanese adults [23].

Limitations

Immediately after the earthquake struck, an ethical decision was made to refrain from sending reminder emails. Therefore, the response rate was low during this period. However, no significant difference in the daily prevalence of insomnia correlated with the use of these reminder emails in either Tokyo or Osaka. The chi-square test results were similar between analysis including and excluding this time period. Although the reminder emails were included in the logistic regression analysis as an independent variable, the presence or absence of the reminder emails inevitably remains a limitation of this study and a potential source of bias. However, we believe that this factor had a negligible effect on the results.

Conclusions

This study examined the prevalence of insomnia among residents in areas distant from the epicenter of the Great East Japan Earthquake. In Tokyo, where the seismic intensity was higher, both adults and minors experienced increased rates of insomnia as a direct result of the earthquake and its aftershocks. Further, mental stress induced by information broadcast by the media may have influenced the prevalence of insomnia. In Osaka, where the seismic intensity was lower, only adults exhibited an increased prevalence of insomnia. Health care practitioners should be aware that individuals might experience mental stress, including insomnia, even in areas distant from those that are directly affected by a natural disaster.

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Conflicts of Interest

None declared.

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Abbreviations

ASD: acute stress disorder
CO-OP: Consumers' Co-operative Union
JMA: Japan Meteorological Agency
PTSD: post-traumatic stress disorder

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Internet survey of the influence of environmental factors on human health: environmental epidemiologic investigation using the web-based daily questionnaire for health

Tomomi Sano[a]*, Manabu Akahane[a], Hiroaki Sugiura[a], Yasushi Ohkusa[b], Nobuhiko Okabe[b†] and Tomoaki Imamura[a]

[a]*Department of Public Health, Health Management and Policy, Nara Medical University School of Medicine, 840 Shijo-cho, Kashihara, Nara 634-8521, Japan;* [b]*National Institute of Infectious Disease, Infectious Disease Surveillance Center, 1-23-1 Toyama, Shinjuku-ku, Tokyo 162-8640, Japan*

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With increasing Internet coverage, the use of a web-based survey for epidemiological study is a possibility. We performed an investigation in Japan in winter 2008 using the web-based daily questionnaire for health (WDQH). The WDQH is a web-based questionnaire survey formulated to obtain information about the daily physical condition of the general public on a real-time basis, in order to study correlations between changes in physical health and changes in environmental factors. Respondents were asked whether they felt ill and had specific symptoms including fever. We analysed the environmental factors along with the health conditions obtained from the WDQH. Four factors were found to influence health: minimum temperature, hours of sunlight, median humidity and weekday or holiday. The WDQH allowed a daily health survey in the general population in real time via the Internet.

Keywords: web-based survey; environmental factor; minimum temperature; general population

Background

With the rapid progression of Internet technology, a web-based epidemiological survey was developed and implemented for use with the general public (Ekman and Litton 2007). This allowed epidemiological studies to be conducted at lower cost, with greater speed and with higher data precision compared with paper-based or face-to-face surveys on a similar scale (Bennett et al. 2007; Ekman and Litton 2007). Although early web-based surveys were found to be problematic because of population bias, this has been mitigated with the marked increase in the proportion of the population using the Internet (Ekman et al. 2006).

Web-based epidemiological studies came to be implemented for cross-sectional studies as well as for follow-up investigations (Bennett et al. 2007). To date, web-based follow-up surveys have been conducted with patients with specific diseases, but

*Corresponding author. Email: sanotomo@naramed-u.ac.jp
†Present address: Kawasaki City Institute for Public Health, 5-13-10 Oshima, Kawasaki-ku, Kawasaki city, Kanagawa, 210-0834, Japan.

not with the general public. Specifically, no studies have been conducted to investigate the correlations between daily environmental changes and the daily physical condition of members of the general public. There is currently concern over human health with regard to air pollution (Huang et al. 2009) and global warming (McMichael et al. 2006). Accordingly, it would be useful to be able to determine the influence of environmental factors on the health of the general population on a daily basis. Therefore, we developed a follow-up survey system using the Internet to question citizens directly on a daily basis. We named this survey the web-based daily questionnaire for health (WDQH).

We then studied the correlations between changes in the daily physical condition of the subjects and changes in environmental factors that are considered to have an influence on health (minimum temperature, hours of sunlight, median humidity, weekday or holiday) using the WDQH.

Methods

Survey method

The WDQH is a prospective survey system designed to conduct a direct health-related questionnaire survey of individuals every day for a certain period to collect and analyse information on a real-time basis. The WDQH has already been put into operation in part, and its usefulness has been established (Sugiura et al. 2010).

Participants

Participants were persons already registered with an existing internet survey company, who noticed the request to participate in the questionnaire survey on the company website, and voluntarily decided to participate. They understood the purpose of the survey, and that it also included information on their families. In this survey, the residential area of the participants was limited to Izumo, a regional city in Japan. We only included those who understood the details of our request and agreed to cooperate in the survey. The population of Izumo is approximately 150,000, with approximately 50,000 households. The study included 702 subjects (333 males, 369 females; mean age 37.4 years; range 16 72 years) from 181 households. We collected information describing the survey participants including their residential district, age, gender, occupation, marital status, number of children and annual income. The survey was performed for 78 days from January 10, 2008 to March 28, 2008.

Questionnaire

The survey required participants to answer questions regarding subjective symptoms every day. The internet survey company sent a reminder email to each subject daily requesting completion of the questionnaire survey. The subject opened the email, accessed his/her personal password and then answered the questionnaire about himself/herself and his/her family. Respondents were asked whether they felt ill. If not, they closed the survey on that day. Those who answered in the affirmative were then asked detailed questions about whether they had any of the following symptoms: fever, coughing, diarrhoea, vomiting, rash, convulsion and others. Remuneration (approximately 60 yen/answer: US$ 0.75; US$1.00 = 80 yen at the time of writing) was given to the registered monitors. The survey was repeated every

day over the study period. We analysed and studied the correlations between changes in the daily physical condition of the participants and changes in environmental factors.

Environmental factors

Data describing the following 12 environmental factors are monitored and published by The Japan Meteorological Agency: mean temperature, maximum temperature, minimum temperature, hours of sunlight, cloud cover (the percentage or fraction of the sky obscured by clouds represented by an 11-point scale), median humidity, atmospheric pressure, vapour pressure, precipitation, wind direction, wind speed and weekday or holiday. Data describing these environmental factors in the survey area were collected. Mondays to Fridays were considered weekdays, while Saturdays, Sundays and public holidays were considered to be holidays.

In addition, three individual factors (sex, age and annual income) were included.

The 15 variables were first subjected to principal component analysis. As a result, five principal components were identified. The first component was temperature; the second component was hours of sunlight; the third components were sex and age; the fourth component was wind direction; and the fifth component was median humidity.

Then, the correlation coefficients of all 15 variables were examined. Eight variables (sex, age, annual income, median humidity, precipitation, wind direction, wind speed and weekday or holiday) were included because of no correlations between them. Cloud cover, vapour pressure and atmospheric pressure, which were not extracted as main components and showed strong correlations (correlation coefficient >0.5), were excluded from the variables. Mean temperature was strongly correlated with maximum temperature ($r = 0.924$) and minimum temperature ($r = 0.722$). Hence, a single variable could be selected from mean temperature, maximum temperature and minimum temperature. Minimum temperature, which was not correlated with hours of sunlight ($r = -0.097$), was selected as a variable to negate interaction with hours of sunlight, which was selected as the second component for principal component analysis. Thus, 10 variables were selected: sex, age, annual income, minimum temperature, hours of sunlight, median humidity, precipitation, wind direction, wind speed and weekday or holiday.

Additionally, the 10 selected variables were analysed using generalized estimating equations (GEE). Three variables (precipitation, wind direction and wind speed) showed no significant correlation with any independent variable (ill or healthy and details of symptoms) and were excluded from covariates by a stepwise method. The variables remaining in the final analysis included four environmental factors (minimum temperature, hours of sunlight, median humidity and weekday or holiday).

Statistical analysis

Statistical analysis was conducted using IBM SPSS 20. A p-value <0.05 was considered to indicate significance. Adjusted odds ratios and standard deviations were determined with 95% confidence intervals.

The data used in this study were answers repeatedly collected from the same subject to the same question. We selected the GEE useful for the analysis of repeated

measurements of health results. The repeated measurements included individuals and households as subject variables and days as an intra-subject variable.

Generalized estimating equations was conducted using "ill or healthy" as a dependent variable and three individual factors (sex, age and annual income) and four environmental factors (minimum temperature, hours of sunlight, median humidity and weekday and holiday) as independent variables. The GEE was also performed using presence/absence of specific symptoms (fever, coughing, diarrhoea, vomiting, rash and others) as a dependent variable, and the seven aforementioned independent variables.

Ethics and consent

This research was conducted with the approval of the Ethics Committee of Nara Medical University (Authorization code: 220).

Results

The largest age group of the enrolled subjects was between 35 and 39 years old (37 years old on average) for both males and females. The ratio of males to females of the participants was approximately 1:1. The male and female participants were similar in age distribution. Approximately, 500 completed questionnaires were received each day during the survey period, giving a daily response rate of 35% to 51% (47% on average) (Figure 1). The mean response rate was 48.7% on weekdays and 44.4% on holidays. The everyday responder rate throughout the survey period was 3.2%. Although 34.5% of persons registered to show his/her willingness to answer the survey, they did not respond. As shown in Figure 2, the proportion of respondents who reported that they felt ill during the survey period ranged from 3% to 10% on a daily basis during the survey period.

Table 1 illustrates the outcome of the questionnaire according to gender. There were more female respondents than male respondents who suffered changes in their

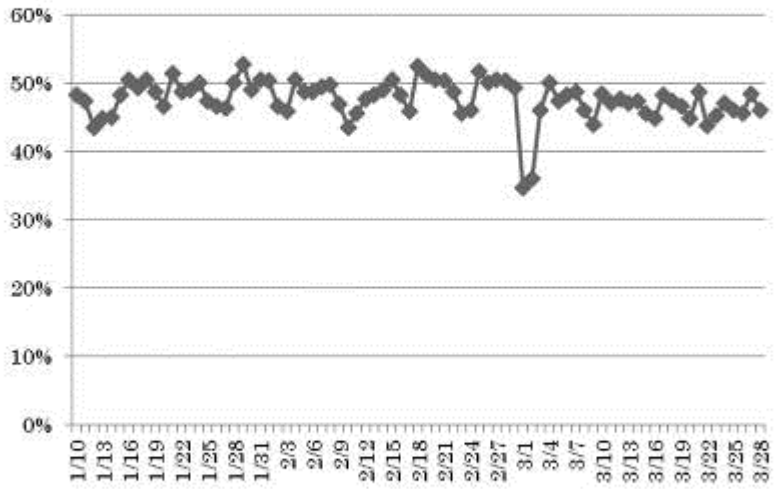

Figure 1. Daily response rate to the questionnaire.

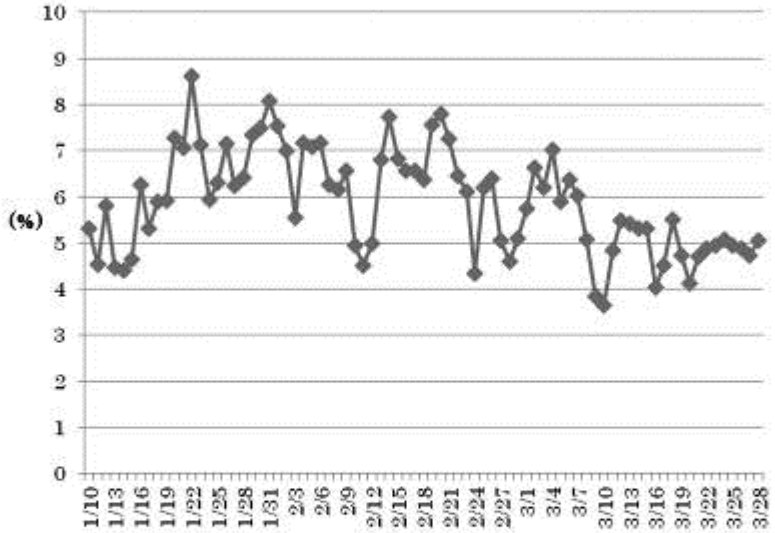

Figure 2. Proportion of respondents who answered that they were ill on specific days.

Table 1. Questionnaire outcomes.

	Male		Female		Total	
	Presence of symptoms (%)	Absence of symptoms (%)	Presence of symptoms (%)	Absence of symptoms (%)	Presence of symptoms (%)	Absence of symptoms (%)
Ill	1746 (5.7)	28,830 (94.3)	2246 (6.9)	30,274 (93.1)	3992 (6.3)	59,104 (93.7)
Fever	247 (0.8)	30,329 (99.2)	249 (0.8)	32,271 (99.2)	496 (0.8)	62,600 (99.2)
Coughing	944 (3.1)	29,632 (96.9)	958 (2.9)	31,562 (97.1)	1902 (3)	61,194 (97)
Diarrhoea	117 (0.4)	30,459 (99.6)	181 (0.6)	32,339 (99.4)	298 (0.5)	62,798 (99.5)
Vomiting	94 (0.3)	30,482 (99.7)	116 (0.4)	32,404 (99.6)	210 (0.3)	62,886 (99.7)
Rash	28 (0.1)	30,548 (99.9)	34 (0.1)	32,486 (99.9)	62 (0.1)	63,034 (99.9)
Convulsion	19 (0.1)	30,557 (99.9)	2 (0)	32,518 (100)	21 (0)	63,075 (100)
Others	768 (2.5)	29,808 (97.5)	1602 (4.9)	30,918 (95.1)	2370 (3.8)	60,726 (96.2)
Sum total	30,576		32,520		63,096	

physical condition. Coughing accounted for the highest proportion (3%) of an individual symptom suffered by respondents during the survey period.

From principal component analysis, the first principal components were mean temperature, maximum temperature and minimum temperature. The second principal component was hours of sunlight. The third principal components were sex and age. The fourth principal component was wind direction. The fifth principal component was median humidity.

Pearson's correlation coefficients were calculated. Variables strongly correlated were as follows: mean temperature and maximum temperature ($r = 0.924$; $p < 0.001$), mean temperature and minimum temperature ($r = 0.722$; $p < 0.001$), mean temperature and atmospheric pressure ($r = -0.547$; $p < 0.001$), mean temperature and vapour pressure ($r = 0.880$; $p < 0.001$), maximum temperature

and hours of sunlight ($r = 0.566$; $p < 0.001$), maximum temperature and cloud cover ($r = -0.579$; $p < 0.001$), maximum temperature and vapour pressure ($r = 0.779$; $p < 0.001$), minimum temperature and atmospheric pressure ($r = -0.520$; $p < 0.001$), minimum temperature and vapour pressure ($r = 0.760$; $p < 0.001$), atmospheric pressure and vapour pressure ($r = -0.521$; $p < 0.001$).

Table 2 shows the results of the GEE of ill participants. The number of ill subjects was inversely proportional to individual factors (age and annual income) and environmental factors (minimum temperature and hours of sunlight). In addition, fewer people were found to be ill on holidays.

Table 3 shows the results of GEE of individual symptoms. The results revealed that the number with fever, cough, diarrhoea, vomiting and rash decreased with age. Others (unidentified complaints) decreased as annual income increased. Fever and rash decreased as the minimum temperature increased. Additionally, fever and vomiting decreased as hours of sunlight increased. On holidays, cough and others decreased and rash increased.

Discussion

In the present study, the relationship between environmental factors and health conditions, which changed on a daily basis, were analysed from health results in the daily web questionnaire survey. Case control designs, generalized linear models (GLIM), and GEE are useful for such repeated epidemiological analyses. The GEE was established by modifying GLIM, and has been found to be useful for repeated measurements and longitudinal data analysis. The GEE allows unbiased estimation and bias correction for individual confounding factors that may be generated from Internet survey results. They are commonly used in large epidemiological studies, especially multi-site cohort studies as they can handle many types of unmeasured dependence between outcomes (Nitta et al. 2010). Thus, we employed GEE for analysis of the repeated measurements of health results in our web survey to analyse the changes in environmental and health conditions.

Correlations between environmental changes and changes in daily symptoms have been reported for particular diseases (Vocks et al. 2001; Srinivasan et al. 2007; Pantavou et al. 2008). A decrease in temperature is associated with an increase in ischemic cardiac events such as angina pectoris and a rise in blood pressure, while an

Table 2. Generalized estimating equations of ill subjects.

	Ill		Healthy		GEE			
	Mean	SD	Mean	SD	*B*	SE	*p*-value	Exp(B)
Sex					0.099	0.2440	0.686	1.104
Age	36.15	6.460	37.90	9.000	−0.023	0.0111	0.035**	0.977
Annual income	3.07	1.499	3.53	1.609	−0.197	0.0893	0.027**	0.821
Minimum temperature	5.078	2.8328	5.359	2.9440	−0.029	0.0128	0.024**	0.972
Hours of sunlight	2.873	3.1088	3.163	3.2276	−0.030	0.0111	0.007**	0.971
Median humidity	76.47	7.411	76.08	7.353	0.002	0.0035	0.563	1.002
Weekday or holiday					0.122	0.0474	0.010**	1.130

Notes: $^{**}p < 0.05$; $^{*}p < 0.1$. The table shows the mean and standard deviation (SD) based on the presence/absence of symptoms for comparison. GEE: generalized estimating equations; SE: standard error.

Table 3. Generalized estimating equations for each symptom.

	Symptom present		No symptom		GEE			
Fever	Mean	SD	Mean	SD	*B*	SE	*p*-value	Exp(B)
Sex					0.046	0.2661	0.862	1.048
Age	34.78	6.924	37.82	8.895	−0.044	0.0110	0.000**	0.957
Annual income	3.70	1.591	3.50	1.607	0.073	0.0637	0.250	1.076
Minimum temperature	4.655	2.5315	5.348	2.9407	−0.058	0.0270	0.031**	0.944
Hours of sunlight	2.578	2.8574	3.151	3.2239	−0.076	0.0254	0.003**	0.926
Median humidity	76.31	7.231	76.10	7.358	−0.009	0.0088	0.32	0.991
Weekday or holiday					0.080	0.1347	0.554	1.083
Coughing								
Sex					0.384	0.2593	0.138	1.469
Age	36.06	5.545	37.85	8.954	−0.029	0.0080	0.000**	0.971
Annual income	3.51	1.359	3.50	1.613	−0.010	0.0650	0.882	0.990
Minimum temperature	5.015	2.8145	5.352	2.9413	−0.042	0.0223	0.062	0.959
Hours of sunlight	2.772	3.0623	3.157	3.2254	−0.034	0.0181	0.058	0.966
Median humidity	76.85	7.592	76.08	7.349	0.008	0.0057	0.145	1.008
Weekday or holiday					0.222	0.0697	0.001**	1.248
Diarrhoea								
Sex					−0.113	0.3287	0.732	0.894
Age	35.49	6.418	37.81	8.893	−0.030	0.0146	0.038**	0.970
Annual income	3.55	1.664	3.50	1.607	0.026	0.0905	0.773	1.027
Minimum temperature	5.112	2.9279	5.344	2.9386	0.019	0.0369	0.611	1.019
Hours of sunlight	2.794	3.2217	3.148	3.2217	−0.032	0.0376	0.396	0.969
Median humidity	76.55	7.174	76.10	7.357	0.002	0.0120	0.889	1.002
Weekday or holiday					−0.156	0.1906	0.414	0.856
Vomiting								
Sex					−0.109	0.3291	0.741	0.897
Age	34.26	7.620	37.81	8.887	−0.046	0.0214	0.032**	0.955
Annual income	2.97	1.632	3.50	1.607	−0.217	0.1449	0.134	0.805
Minimum temperature	4.371	2.5365	5.346	2.9391	−0.051	0.0462	0.271	0.950
Hours of sunlight	2.050	2.5977	3.150	3.2228	−0.135	0.0469	0.004**	0.874
Median humidity	77.35	6.879	76.10	7.358	0.001	0.0171	0.933	1.001
Weekday or holiday					−0.034	0.2165	0.874	0.966
Rash								
Sex					1.185	1.0015	0.237	3.270
Age	28.43	3.664	37.81	8.885	−0.199	0.0326	0.000**	0.617
Annual income	3.69	1.814	3.50	1.607	0.053	0.2451	0.827	1.055
Minimum temperature	4.786	2.9974	5.344	2.9385	−0.144	0.0643	0.025**	0.866
Hours of sunlight	3.017	3.0967	3.147	3.2220	−0.019	0.0625	0.762	0.981
Median humidity	76.12	7.510	76.10	7.357	0.004	0.0172	0.838	1.004
Weekday or holiday					−0.483	0.2155	0.025**	0.617
Others								
Sex					−0.440	0.3542	0.214	0.644
Age	36.55	6.917	37.84	8.938	−0.002	0.0147	0.913	0.998
Annual income	2.43	1.222	3.53	1.606	−0.654	0.1765	0.000**	0.520
Minimum temperature	5.214	2.8481	5.347	2.9413	−0.020	0.0150	0.189	0.981
Hours of sunlight	3.041	3.1820	3.151	3.2230	−0.017	0.0130	0.198	0.983
Median humidity	76.08	7.301	76.10	7.359	−0.003	0.0042	0.426	0.997
Weekday or holiday					0.147	0.0609	0.016**	1.159

Notes: $^{**}p < 0.05$; $^{*}p < 0.1$.

increase in minimum temperature, especially during the warm season, is associated with a decrease in the onset of cardiovascular or respiratory events (Pantavou et al. 2008). It has also been reported that a decrease in humidity at a temperature of less than 15°C resulted in an increase in the rate of torsion of the testes (Srinivasan et al. 2007). A sharp decrease in temperature has been reported to exacerbate symptoms such as itching sensations in patients with atopic dermatitis (Vocks et al. 2001). Moreover, an increase in maximum temperature of 1°C was found to increase overall mortality by 0.9%, and a mean temperature of 32°C or above has been reported to increase overall mortality by 7.3% (Hu et al. 2008). An article about the relationship between climate and hospitalization in children with asthma demonstrated that children aged 0 4 years were the most vulnerable to climatic changes. More children were hospitalized on cold and dry days with low absolute humidity (Nastos et al. 2008). An article on the relationship between climate and respiratory infection demonstrated that temperature and humidity were strongly associated with the development and aggravation of respiratory infection. Of note, there was an increase in death rate about two weeks after cold days with low humidity (Nastos et al. 2006). An article on the relationship between climatic changes and death rates demonstrated that rapid climatic changes were a critical risk factor for death. Of note, the physical conditions are influenced at three days in winter and at one day in summer after rapid climatic changes (Nastos et al. 2011).

However, few studies have been conducted to investigate the correlation between changes in the daily physical condition of a general population not suffering from any particular disease, and changes in environmental factors.

When ambient temperature decreases during winter, symptoms such as runny nose, sneeze, cough or fever commonly appear. Moreover, bacterial infections, common cold and influenza are frequently reported to increase during winter in clinical practice (Heikkinen and Järvinen 2003; Tanaka 1998). These correspond to the result that when the minimum ambient temperature decreases, it is likely that many people will experience symptoms of poor health, especially fever. Conversely, when the minimum ambient temperature increases, the overall health conditions of the general population tend to improve. The web-based questionnaire collects data regarding changes in the respondents' daily physical condition on a real-time basis, which allowed investigation of the correlation between environmental factors and the physical condition of the general population.

The results also revealed that the physical condition of the respondents improved as the hours of sunlight increased. Additionally, more people were ill on weekdays than on holidays. It is possible that the latter finding was related to stress. Indeed, an increase in the prevalence of disease caused by psychosocial stress in recent times has been reported (Schmidt et al. 2008), and attending school or work on a weekday may result in psychosocial stress, which could have an effect on the physical condition. In contrast, a more relaxing time on holiday is likely to relieve stress (Butler et al. 2009) and improve the physical condition.

The "presence/absence of specific symptoms" was found to be significantly correlated with hours of sunlight. Hours of sunlight has been reported to be correlated with the secretion of serotonin in the brain; therefore, mental disorders such as depression and anxiety, which are associated with decreased serotonin secretion, may be improved by sunlight exposure (Lambert et al. 2002). In addition, ultraviolet exposure increases the synthesis of vitamin D, and appropriate quantities of vitamin D may be a preventative factor against immune-related disorders, such as

multiple sclerosis and type 1 diabetes mellitus, infections and cancer (Norval et al. 2007). It has also been reported that the risk of human papillomavirus (HPV) infection decreases as the amount of sunlight exposure increases. Despite the reported effects of increased sunlight, the increase in ultraviolet radiation resulting from depletion of the ozone layer could have adverse effects on the body such as acute damage to the eyes and skin. Additionally, sunlight exposure is associated with an increased risk of skin squamous cell carcinoma, epidermodysplasia verruciformis-HPV infection and decreased skin or systemic immunoreactivity (Termorshuizen et al. 2004).

The results of this study revealed that the appearance of symptoms decreased with increased hours of sunlight. These findings were in accordance with the positive effects of sunlight exposure on the human body observed in previous reports.

Although it has been reported that intra-individual variability, amount of sunlight exposure and individual background significantly influenced the effects of sunlight exposure on intracellular DNA, and that ultraviolet-induced DNA damage accumulated over three to six days (Moller et al. 2002), this was not relevant at the time of year our survey was conducted.

An article about the relationship between health conditions and individual factors indicated that health conditions varied with sex, age and income. Men were more vulnerable than women. Younger persons were more vulnerable. Those with higher incomes had better health conditions (Belloc et al. 1970). The present survey also demonstrated that individual factors influenced health conditions.

It should be noted that there are some limitations to this study. In the questionnaire, the severity and specificity of symptoms in the questions could not be determined by the researcher. This survey was also limited in terms of the assessment of the reliability of respondents' answers due a self-reporting system being used.

The cost of the three-month survey in Izumo was 8.28 million yen (US$ 103,500). It would be ideal to conduct surveys about changes in the environment and health conditions of the general population in major cities in Japan all year long. Although a web-based survey is cheaper than paper-based or face-to-face surveys, if the survey was expanded to main cities in Japan or carried out over a full year, the expense would be massive. Thus, because of the excessive cost of such surveys, the target area and period in this survey were limited. January to March was selected because we assumed that changes in health conditions caused by environmental changes would be most common during the period from winter to spring (specifically January to March). The results of this study demonstrated that changes in body conditions were associated with environmental changes. However, as described above, health conditions and climatic changes have time trends. Thus, a survey should be conducted throughout the year in different seasons and months. In the future, we hope to expand the survey area and study period. In addition, given that sunlight exposure may have an impact on the human body not only on the day of exposure, but three to six days later (Moller et al. 2002), it may be necessary to perform a more detailed analysis using lag times to investigate the correlation of sunlight with physical condition.

Conclusions

The WDQH enabled monitoring of changes in physical condition on a real-time basis by daily collection of data. Changes in the daily physical condition of the

general population were found to be correlated with changes in certain environmental factors. In particular, it was revealed that the following factors in winter/spring were associated with physical condition: fever, cough, diarrhoea, vomiting and rash decreased with age. Others decreased as household income increased. An increase in minimum temperature was associated with a reduction in fever and rash; an increase in hours of sunlight was associated with a reduction in fever, and vomiting; holidays were associated with better physical condition and less coughing and others, while rash increased.

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第12回集会から

■セッションⅠ

食品防御から見たバイオリスク認知・バイオリスク評価・バイオリスクマネジメントの考え方と食品バイオテロに対する食品防御による対応

今村 知明
奈良県立医科大学健康政策医学講座

はじめに

人類の食、それは常に危険と隣り合わせの歴史の上に現在の安全が成り立っている。現在我々が口に入れているもの全てがハザードと言っても過言ではない。しかし、ハザードによる悪影響とそのハザードとなり得る可能性、つまりリスクの大きさは、毒性の強さと摂取する量により変わる。

それらは、人類の長年の経験で自然に身についてきた知識となり食の安全が保たれるようになった。しかし、近年、ライフスタイルの多様化と共に、日常生活で占めるウェイトの高い食生活も多様化を極め、食に関する問題は多岐に渡るようになった。

中でも、9.11 世界同時多発テロ事件とほぼ時を同じくして起こった炭疽菌事件を機にバイオテロが注目され、そのターゲットになりやすい食品へのテロ対策の重要性が高まってきた。日本でも、毒入り餃子事件などで意図的な食品汚染に関する具体的対策が急務となった。

そこで、食品防御から見たバイオリスク認知・バイオリスク評価・バイオリスクマネジメントの考え方と食品バイオテロに対する食品防御による対応について述べる。

食品安全とは

食品の安全とはどのように考えるべきだろうか。

夏場日中に常温で放置した刺身は、もはや「食べ物」ではなく、むしろ、食中毒により命を落とす危険が生じた「毒物」である。この変化は容易く起こるものであり、この変化こそが食べ物の本質である。容易く「毒物」に変化してしまうものを普段食べているという認識が大切なのだ。食品添加物などを恐れるのは、次のステップである。

冒頭でも述べたように、そもそも食品とは危険でリスクのあるものである。ジャガイモの青芽は毒性のアルカロイドを含み、メークインを数日間日光に当てて緑色になった部分や青芽だけを集めたら、成人中毒量（200 mg）を超えることもある。また、コーヒーに含まれる一般的なカフェインの量を食品添加物として使用すると、食品添加物の基準から見て、流通が認められることはないと考えられる。では、なぜそんな危険なものを口にしているのか。それは、多数の人間が長期にわたり実際に食べて大丈夫であったことが、その食品を食べることの安全性を示していると言える。そうして、現在はジャガイモもコーヒーも危険という認識を持たずに安心して口にすることができている。

では、新たに発見された食品の毒性について食の安全は保たれているだろうか。これには、リスクに対する過剰反応が伴い、安全という認識がしばしば置き去りにされている。2000 年代初頭に発生した BSE 問題を例に取ると、我が国における BSE 問題による vCJD の患者数は英国の滞在歴のある者１名であるにもかかわらず、この問題による関係者の自殺者数は酪農家など５名にものぼる。これはリスコミュニケーションがうまくいっていない事が大きな原因だと思われ、いかに正しい情報を過剰反応せずに理解するか、が食品の安全につながると言える。また、残留農薬などの食の安全性に関する諸問題も発生したが、いずれも、消費者等における不明確なリスクや不可視なリスクに対する実際のリスク以上の反応、という問題が伴い、本来の食品の安全に対しての正しい評価が難しくなるのである。

しかし、2008年の冷凍ギョーザ事件では、残留農薬等の食の安全性にかかわる一般的な問題ではなく、食品を犯罪やテロからいかに防ぐかという食品防御に係る問題が新たに俎上に上り、リスク回避と危機管理体制の構築の必要性に迫られた[1]。

食品防御でのリスクの認知とバイオリスクの認知

それ以前から、2001年9.11テロ後の炭疽菌事件など世界各国でのバイオテロの危険性が指摘されていた。そして、そのターゲットとして食品のリスクは非常に高いものと考えられた。特に、米国では食品産業の危険性を認識し積極的な対策措置が講じられるようになった。しかし、テロ対策にはグローバルな各国の協調が不可欠である。それに加え、前述の冷凍ギョーザ事件が発生するなど、我が国でも食品防御の対策の検討が必要となった。

従来の食品安全に対する信頼を脅かす事例が発生し、意図的な食品汚染に対して脆弱な製造現場が明らかになってきた。

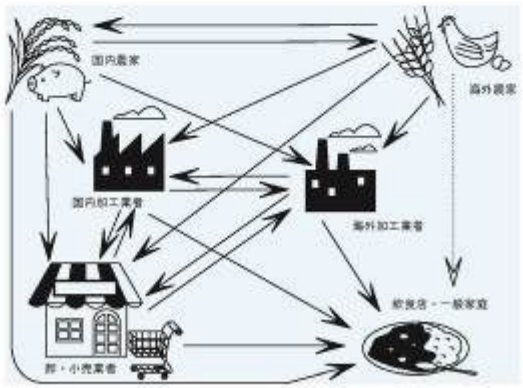
食品工場への聞き取りによると、

○意図的な食品汚染への備え（"管理部門や責任者の設置"、"計画・手続きの策定"、"評価の実施"）を行っている工場はほとんどない

○工場内に監視カメラはあるものの、従業員の作業状況をチェックする目的のものではない（⇒そもそも、従業員の心理面を考慮すると、従業員の作業状況をチェックするためのカメラ設置は現実的ではない）

等、特に、食品テロのように「悪意」をもって食品に毒物が混入されるような場合には、極めて弱いのである。

食品の流通経路は一般に「フードチェーン」と呼ばれている。この複雑なチェーンのどの部分が汚染された場合でも、多方面に大きな被害が生じる。そして、今、食品の流通はグローバル化が進み、流通経路も複雑になり汚染物質の持ち込みはますます防ぎにくくなっているのである[2]。



食品防御でのリスク評価とバイオリスク評価

では、食品防御におけるリスク評価、バイオリスク評価はいかに行うべきか。

それには、食品防御の脆弱性をチェックする方法が挙げられる。つまり、「何を用いてテロを行うか」と、「効率よく効果的に攻撃できるのはどこか」を考えることが重要となる。

アメリカの食品医薬品局（FDA）と農務省（USDA）では、米軍で開発された「CARVER+Shock法」という攻撃に対する弱点を洗い出す手法を、テロ攻撃対象箇所の優先順位付けのツールとして採用している[3-5]。このツールで、食品テロに対するシステムやインフラの脆弱性を評価し、それによって対策を講ずるべき箇所を把握できるので効率的な対策が可能となる。これはフードチェーン全体から個々の施設やプロセスまで、様々な範囲の評価に適用できる。

C	Criticality （消費者への）危険性：	テロによる公衆衛生および経済的影響の度合い ⇒死者数、および経済的損失額によって定量評価
A	Accessibility アクセス容易性：	テロ対象への物理的なアクセスの容易性
R	Recuperability 回復容易性：	テロ後のシステムの回復容易性
V	Vulnerability 脆弱性：	テロの遂行容易性
E	Effect （自社への）影響：	テロによる直接的損失規模（生産量の損失等）
R	Recognizability 認識容易性：	テロ実行における攻撃対象の認識の容易さ
+Shock	衝撃度：	テロにより波及する健康・経済・心理的影響

得点の定量的評価基準の例 Criticality
9-10：死者 1 万人以上、または損失 10 兆円以上
7-8 ：死者 1,000 人～1 万人、または損失 1 兆～10 兆円
5-6 ：死者 100 人～1,000 人、または損失 1,000 億～1 兆円
3-4 ：死者 100 人未満、または損失 1,000 億未満
1-2 ：死者発生なし、または損失 100 億円未満

評価を実施するためには、各分野の専門家から構成されたチームを組織化して臨まなければならない。評価対象のフードサプライチェーンを最小の要素（工程）にまで細分化し構造を図示する。各工程に対して7つの評価項目に関する得点付けを行い（1 ～ 10 点）、総合得点の高い工程は脆弱性が高いと判断する。各工程の総合得点を比較することで、脆弱な工程を明確化することが可能である。この評価をもとに、テロ対象としての魅力度を下げる対策の実施計画を策定することができる[6]。

食品への混入が想定される生物剤・化学剤の要件を下記にまとめる。

生物剤

要件	概要	生物剤の特性上留意すべき点等
致死性	①消費者がターゲット ②企業の信用失墜 ③広く社会的混乱を狙う のそれぞれにより致死性の高さの要件は異なる。	△一般的な食中毒の原因菌：影響小。 △腸管系病原菌（赤痢・コレラ・チフス）：治療法が確立しているため影響小、広まりにくい。
潜伏期間	・対象に依存 ・フードチェーンの段階に依存	？生産側への投入／消費者への暴露など、対象に依存 ？生産・流通・加工・販売などの段階に依存
入手容易性	・入手が容易	○入手・生成しやすいものもしくは一般的な条件下で増殖しやすいもの
可搬性	・取扱い・持ち運びが容易	○取扱いに高度な装置・技術を必要としないもの
安定性	・諸条件下で安定	○毒素：熱に強く効果が高い。 △萌芽：熱に強いが、増殖には一定条件が必要 ×嫌気性病原菌等：酸素の存在下で減少・死滅
実行犯の安全性	・実行犯に被害が及びにくい	－
特定困難性	・容易に特定されない	○検知に時間を要するand/or検知困難なもの

化学剤

要件	概要	化学物質の特性上留意すべき点等
致死性	・致死性が高い （毒性が強い）	○食品によっては生産・加工段階で希釈されるものがあるため、少量で高い毒性を持つもの（LD50値が低いもの）
潜伏期間	―	―
入手容易性	・入手が容易	○入手・製造が容易であるもの
可搬性	・取扱い・持ち運びが容易	○取扱いに高度な装置・技術を必要としないもの
安定性	・諸条件下で安定、食品に混入された状態が保てる	○揮発性物質ではないもの（水に溶解するもの）
実行犯の安全性	・実行犯に被害が及びにくい	○特に、揮発性でないもの
特定困難性	・容易に特定されない	○特に、無色・無臭であるもの ○検知に時間を要するand/or検知困難なもの

ここでCARVER+Shock法を参考として、我が国において脆弱性評価を試行し、その有効性を検証した例を紹介しよう。

食　品	対象とした理由
牛乳	先進的な衛生管理の下で製造されてはいるが実際に食中毒の発生事例がある
お弁当	製造工程において多くの人の手に触れる可能性がある
納豆	日本特有の食品であり、またその大部分が小規模の工場で製造されている
給食	子どもに被害が発生する可能性が高い
清涼飲料	
プロセスチーズ	
冷凍食品	実際に被害が発生した
ドレッシング	米国でドレッシング汚染事例あり
冷凍・冷蔵食品取り扱い倉庫	製造工程以外の結節点における検討の必要性
ドライ品取り扱い倉庫	

上に挙げた牛乳について牛乳工場を総括評価した例を示す。ただし、この例により脆弱ポイントが明らかになる危険性があるのでその部分は＊等によって伏せておく。

ポイント		混入の可能性	相対評価
○○○○		・＊＊＊＊＊であり、誰でも容易に近づくことができる状態にあった。また、＊＊は施錠がされていない状態であった。 ・＊＊＊＊＊であれば人的被害を及ぼすのに十分な物質を投入可能と考えられる。 ・＊＊＊＊＊ており、非専門家でも攻撃対象の認識が容易である。 ・以上の理由から、＊＊＊＊＊から攻撃を受ける可能性が相対的に高いポイントであると言うことができる。	脆弱性が高い
殺菌	清浄化 均質化 殺菌 冷却・貯乳(屋上)	・＊＊＊＊＊のため、外部からのアクセスは困難であると考えられる。 ・また、＊＊＊＊＊のシステムとなっており、一度に大量の物質の投入は困難であると考えられる。 ・但し、＊＊＊＊＊で作業を行ない、＊＊＊＊＊により製造中の牛乳に(一応は)触れることができる。加えて、＊＊＊＊＊も無く、日常的に＊＊＊＊＊を行なっているなど、ラインに手を触れる光景がそれほど特異なものと映らない。 ・以上より、攻撃は困難であるが、内部犯行の可能性には留意する必要があると考えられる。	脆弱性は低いが、施設・機器を熟知した内部犯行の可能性には留意する必要がある
検査 充填 冷蔵保管		・短期間での大量投入が困難であり、攻撃の危険性は比較的低いと考えられる。	脆弱性は低い
出荷		・常時＊＊＊＊＊多くの人が係っており、その中にまぎれて犯行を遂行することも考えられる。 ・また、＊＊＊＊を装えば外部からアクセスすることも容易であり、攻撃対象の認識性も高い。 ・一方で、出荷時には既に小分けされた状態になっており、一度に大量の物質を投入することは困難である。 ・また、商品(攻撃対象年代)、配送先などまで認識することが可能であるという特徴がある点には留意が必要である。 ・以上より、攻撃は比較的容易であるが、甚大な被害を及ぼすような攻撃の危険性は比較的低いと考えられる。但し、グリコ・森永事件のように、少しの攻撃が、企業の経営に多大な経済被害を及ぼす可能性については留意するべきである。	脆弱性は中程度であるが、甚大な被害発生の可能性は低い
全般		・外部メーカー(顔見知りではない場合も多い)の立寄りが多いにもかかわらず、場合によっては＊＊＊＊＊をさせることもあるということであった。攻撃対象へのアクセシビリティの観点から大きな問題であり、何らかの改善が求められる。 ・また、従業員の＊＊＊＊＊、＊＊＊＊＊の詳細な把握が行なわれていないため、内部犯行の可能性にも留意すべきである。	

他の食品についても総括評価を行った試行結果により、下記のセキュリティ強化の必要性が明らかになった。

○人為的な異物混入等に対する食品工場のセキュリティ対策の実施状況は、かなり低いレベルにある。

○特に、上記セキュリティ対策の基本である、現場におけるテロもしくは犯罪行為に対する危険性の認識は、極めて低いものであった。

○これらは、食品製造業における、従業員間・労使間の信頼関係をベースにした運営に起因していると推察される。今後テロや犯罪への対策を講じる際には、この運営を「悪意の既存」的なものにシフトしていく必要がある。

このような運営により、テロや犯罪に対するセキュリティ水準のみならず、食品衛生の管理水準も向上することが期待できる。

しかし実際にこの方法を取り入れるには、食品企業でも多くの労力が必要である。各企業の人的要因や経済的な負担を考慮すると、中小零細規模の食品工場が取り組む課題としては困難であると考えられる。そのため、日本の実情に応じた脆弱性評価手法の開発が必要となった。

食品防御でのリスクマネジメントとバイオリスクマネジメント

そこで、食品関連施設の現場において、脆弱性を比較的簡単に評価できる手法で日本の実情に合ったものが有用であると考え、まず、「食品工場における人為的な食品汚染防止に関するチェックリスト」を作成した[※1]。

※1 平成18～20年度厚生労働科学研究費補助金（食品の安心・安全確保推進研究事業）「食品によるバイオテロの危険性に関する研究」（研究代表者：今村知明）研究班による[7]。

その構成は、1.組織マネジメントについて、2.従業員の管理について、3.部外者の管理について、4.施設の管理について、5.運営の管理について、の5分野計94項目である。

さらに、食品防御は製造過程だけでなく商品が手元に届くまでの物流の過程でも必要であることから、食品工場版のチェックリストにTAPA-FSR[※2]を参考にした物流施設における視点を補足して、「物流施設版チェックリスト」を上記同様5分野で計98項目を作成した。

※2 TAPA（Transported Asset Protection

Association）1997年設立、米国の非営利団体による、資産セキュリティに関する要求事項（Freight Security Requirements）

チェックリストは下記よりダウンロードが可能である。

「食品工場における人為的な食品汚染防止に関するチェックリスト」について
http://www.naramed-u.ac.jp/~hpm/pdf/ff_checklist/ff_checklist_h22ver.pdf

「食品に係る物流施設における人為的な食品汚染防止に関するチェックリスト」について
http://www.naramed-u.ac.jp/~hpm/pdf/df_checklist/df_checklist_h22ver.pdf

そしてこれらチェックリストをベースに食品防御ガイドライン（案）の策定を行った(※3)。

※3 平成21～23年度厚生労働科学研究費補助金（食品の安全確保推進研究事業）「食品防御の具体的な対策の確立と実行可能性の検証に関する研究」（研究代表者：今村知明）研究班による[8]。

ガイドラインは、本来であれば米国のように、人為的な食品汚染の危険性が関係者全般に広く認知された状況下で、各工場における防御対策実施の要件として公表されることが望ましい。しかし、わが国は未だ米国のような状況にない。そこで、より多くの食品関係事業者が人為的な食品汚染の危険性に関心を持ち、現実的に可能な対策を検討することができるように、2つの推奨レベルに分けて作成した。その構成「1. 優先的に実施すべき対策」と、「2. 可能な範囲での実施が望まれる対策」について解説する[9]。

1 優先的に実施すべき対策

■ 組織マネジメント

①食品工場の責任者は、日ごろから全ての従業員等(*)が働きやすい職場環境の醸成に努める。これにより、従業員等が自社及び自社製品への愛着を高め、自社製品の安全確保について高い責任感を感じながら働くことができるような職場づくりを行う。

(*) 派遣社員、連続した期間工場内で業務を行う委託業者などについても、同様の扱いが望まれる。

②食品工場の責任者は、自社製品に意図的な汚染が疑われる事態が発生した場合、消費者や一般社会から、その原因としてまず内部の従業員等に対して疑いの目が向けられる可能性が高いことを、従業員等に意識付けておく。

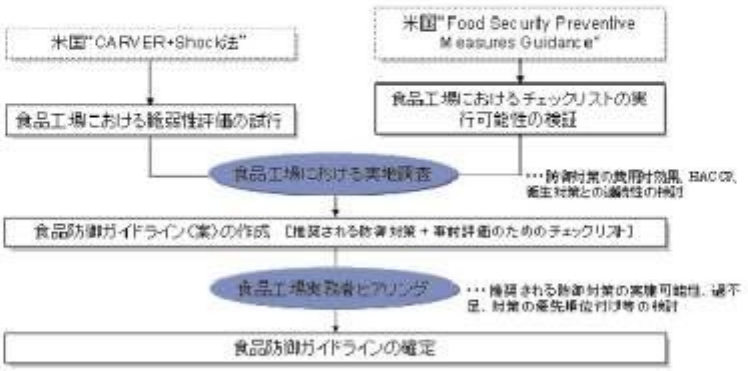
③自社製品に意図的な汚染が疑われる事態が発生した場合において、その原因、経過等について迅速に把握、情報公開ができるよう、普段から従業員の勤務状況、業務内容について正確に把握しておく。

④製品の異常を早い段階で探知するため苦情や健康危害情報等を日常的に確認するとともに、万一、意図的な食品汚染が発生した際に迅速に対処できるよう、意図的な食品汚染が疑われる場合の社内外への報告、製品の回収、保管、廃棄等の手続きを定めておく。

■ 人的要素（従業員等(**)）

(**) 派遣社員、連続した期間工場内で業務を行う委託業者などについても、同様の扱いが望まれる。可能であれば、"食品防御に対する留意"に関する内容を、契約条件に盛り込む。

①従業員等の採用面接時において、可能な範囲で身元確認を行う。例えば、身分証、各種証明書



等について、（複写ではなく）原本の提示を受ける、面接を通じて記載内容に虚偽が無いことを確認する、資格及び職歴の確認を行う、等の手続きをとる。
②従業員等の異動・退職時等に制服や名札、IDバッジ、鍵（キーカード）を返却させる。
③製造現場内への持ち込み可能品リストを作成し、これが遵守されていることを確認する。
④従業員等の従来とは異なる言動、出退勤時間の著しい変化等について把握をする。
⑤従業員の識別・認識システムを構築する。新規採用者については、朝礼等の機会を用いて紹介する等、従業員に認知させる。

■ 人的要素（部外者）

①事前のアポイントがある場合、訪問者に対して身元・訪問理由・訪問先（部署・担当者等）を確認し、可能な限り従業員が訪問場所まで同行する。
②事前のアポイントがなく、かつ初めての訪問者に対して、訪問希望先の従業員に面識の有無、面会の可否を確認した上で、敷地内の立ち入りを認める場合は、事前のアポイントのある訪問者と同様の対応を行う。
③訪問者の種類別に、車両のアクセスエリア、荷物の持ち込みエリアを設定し、訪問者に周知する。
④施設のメンテナンスや防虫･防鼠作業等のため、工場内を単独で行動する必要のある訪問者に対しては、持ち物を十分確認し、不要なものを持ち込ませないように留意する。食品取扱いエリア／保管エリア／ロッカールームに立ち入る場合は特に留意する。
⑤郵便、宅配便の受け入れ先（守衛所、事務所等）を定めておく。また配達員の敷地内の移動は、事前に設定した立ち入り可能なエリア内のみとし、配達員が建屋内に無闇に立ち入ることや、建屋外に置かれている資材・原材料や製品に近づくことができないように留意する。

■ 施設管理

①不要な物、利用者・所有者が不明な物が放置されていないか、定常的に確認を行う。
②食品に直接手を触れることができる仕込み等の工程や、従事者が少ない場所等、意図的に有害物質を混入しやすい箇所を把握し、防御対策を検討する。
③非稼動時における防犯対策を講じる。
④鍵の管理方法を策定する。
⑤製造棟、保管庫については、定期的に鍵の取替えや暗証番号の変更を行う等、外部からの侵入防止対策を適切に行う。
⑥工場内部と外部との結節点を特定し、不必要な又は関係者以外のアクセスの可能性がある箇所については、必要に応じて対策を講じる。
⑦工場内に試験材料（検査用試薬・陽性試料等）や有害物質が存在する場合は、それらの保管場所を定め、当該場所への人の出入り管理を行う。
⑧工場内に試験材料（検査用試薬・陽性試料等）や有害物質が存在する場合は、それらの管理・保管方法、在庫量の確認方法等に係る規定を定め、在庫品の紛失等の異常事態が発生した場合の通報体制を構築する。
⑨殺虫剤の選定基準及び管理・保管方法を策定する。
⑩井戸、貯水、配水施設への侵入防止措置を講じる。
⑪井水を利用している場合、塩素消毒等浄化関連設備へのアクセス管理、監視等を行う。
⑫コンピューター処理制御システムや重要なデータシステムへのアクセス許可者を制限する。
⑬コンピューターのデータ処理に係る履歴を保存する。
⑭従業員の異動・退職時等に、コンピューター制御システムや重要なデータシステムへのアクセス権を解除する。

■ 入出荷等の管理

①資材や原材料等の受け入れ時及び使用前に、ラベルや包装の確認を行う。意図的な食品汚染行為等の兆候・形跡が認められた場合の調査や通報の体制を構築する。
②資材や原材料等の納入時の積み下ろし作業及び製品の出荷時の積み込み作業の監視を行う。
③納入製品・数量と、発注製品・数量との整合性の確認を行う。
④保管中の在庫の紛失・増加や意図的な食品汚染行為等の兆候・形跡が認められた場合の調査や通報の体制を構築する。
⑤製品の納入先から、納入量の過不足（紛失や増加）について連絡があった場合の調査や通報の体制を構築する。
⑥製品の納入先の荷受人（部署）の連絡先について、全ての従業員が確認できるよう、確認の方法を共有しておく。

2 可能な範囲での実施が望まれる対策

■ 組織マネジメント

警備員（社内の警備担当者もしくは警備保障会社職員）に対して、警備・巡回結果の報告内容を明確化する。敷地内における不用物の確認や、異臭等についても報告を受けるようにする。委託を行っている場合、必要であればこれら報告内容を契約に盛り込むようにする。

■ 人的要素（従業員等）

敷地内の従業員等の所在を把握する。

■ 施設管理

①フェンス等により敷地内への侵入防止対策を講じる。

②警備員の巡回やカメラ等により工場建屋外の監視を行う。

③警備員の巡回やカメラ等により敷地内にある有害物質等の監視、施錠確認等を行う。

④警備員の巡回やカメラ等により保管中／使用中の資材や原材料の監視、施錠確認等を行う。

以上、これらガイドラインの項目は、法的な規制や強制力を伴うものではなく、各食品工場において、その規模や人的資源等の諸条件を勘案しながら、「実施可能な対策の確認」や「対策の必要性に関する気付きを得る」ために活用されることを念頭に作成したものである。その趣旨を踏まえた活用を願うものであり、定期的・継続的に確認されることが望ましいと考える。

さらに、ガイドライン（案）のみでは、食品企業がとるべき具体的な対策がわかりづらいとの食品企業の意見を踏まえて、具体的参考となるようにガイドライン（案）の解説も作成した。

厚労省 HP からのリンク　食品の安全確保推進研究事業（厚生労働科学研究）
http://www.mhlw.go.jp/seisakunitsuite/bunya/kenkou_iryou/shokuhin/kenkyu/
社団法人日本食品衛生協会の HP
http://www.n-shokuei.jp/topics/info_guideline.html

おわりに

今、日本の食品企業の 60％は食品テロを想定しておらず、さらにそのうちの 60％は食品テロの可能性は低いと考えているなど、食品テロに対する認識が低いことが指摘されている[10]。現状が続けば「悪意を持った攻撃者」による攻撃や「腹立ちをぶつけたい犯罪者」による異物混入から食品を防御することは困難であると考えられ、食品防御への取り組みはまだまだ不十分だと言える。

食品防御の未発達による相次ぐ食品汚染から顕在化した課題の一つに、食品の広域流通による問題がある。防御しきれなかったために生じてしまう緊急事態を、より早期に発見し的確な対応策をとるために、早期発見システムである「食品における市販後調査（PMM: Post Marketing Monitoring）」の必要性の検討も、今後の課題に含まれるのではないかと考えられる。

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食品汚染防止に関するチェックリストを基礎とした食品防御対策のためのガイドラインの検討

神奈川芳行[1*]　赤羽　学[2*]　今村　知明[2*]　長谷川　専[3*]
山口健太郎[5*]　鬼武　一夫[4*]　髙谷　幸[5*]　山本　茂貴[6*,7*]

目的　世界的に人為的な食品汚染についての関心が高まるに伴い，G8では専門家会合が開催されたり，米国では多くの対策・方針案等が策定されている。しかし，日本では，食品企業の食品テロに対する認識が低く，その脆弱性が危惧されている。今回我々は，日本の食品企業に食品防御対策を普及させるためのガイドライン等を作成した。

方法　すでに作成されている食品工場用チェックリストに示されている食品防御対策について，費用対効果を考慮した「推奨度」を整理した。その推奨度（費用対効果の高い対策順）を基に，「食品防御対策ガイドライン（案）」を作成し，食品工場に対して聞き取り調査を実施した。また，食品防御の観点から，食品工場用チェックリストやガイドラインと「総合衛生管理製造過程承認制度実施要領（日本版HACCP）」を比較した。

結果　推奨度を基に試作したガイドライン（案）に対する食品工場への聞き取り調査を踏まえて，「食品防御対策ガイドライン（食品製造工場向け）」とその解説を作成した。また，食品企業に普及させるために，HACCPにおける食品防御の観点からの留意事項を作成した。

結論　食品防御対策を普及させるためには，食品事業者が使用しやすいガイドラインが有用と考えられた。

Key words：食品汚染，食品防御，食品汚染防止に関するチェックリスト，食品防御ガイドライン，CARVER＋Shock，HACCPの留意事項

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I　はじめに

2001年の世界同時多発テロ以降，世界各国で食品テロの危険性が高まっている。さらに，日本では，食品の期限表示の偽装問題や，中国産冷凍餃子による健康被害の発生により，「食品」の安全に対する関心が高まっている。

日本の食品工場等では，従来から食品衛生の観点から，食品の原材料の受け入れから製造・出荷までのすべての工程において，危害の発生を防止するための重要ポイントを継続的に監視・記録する衛生管理手法であるHazard Analysis Critical Control Point（HACCP）手法を取り入れた総合衛生管理製造過程[1]の導入や，HACCPの食品衛生管理手法をもとにした食品安全マネジメントシステムの国際規格であるInternational Organization for Standardization（ISO）22000[2]に則ったリスク管理が実施されている。しかし，「悪意」をもった食品への毒物の混入には，極めて脆弱であることが危惧されている。

米国では，2003年3月に，食品・薬品を中心に化粧品や玩具，タバコなど，消費者が接する機会の多い製品の認可や違反取締を行う食品医薬品局（Food and Drug Administration; FDA）がGuidance for Industry: Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance（食品セキュリティ予防措置ガイドライン「食品製造業，加工業および輸送業」編）を作成し，食品の製造から輸送過程における食品防御の考え方や対策を示している[3]。さらに，2007年6月には，施設運営者が脆弱性の可能性を特定でき，製品や施設運営

1* 東京大学大学院医学系研究科社会医学専攻
2* 奈良県立医科大学健康政策医学講座
3* ㈱三菱総合研究所
4* 日本生活協同組合連合会
5* (公社)日本食品衛生協会
6* 国立医薬品食品衛生研究所食品衛生管理部
7* 現　東海大学海洋学部水産学科食品科学専攻
連絡先：〒113-8655 東京都文京区本郷7-3-1
東京大学医学部附属病院企画情報運営部
神奈川芳行

の防御強化に役立つようデザインされた脆弱性評価手法である「CARVER＋Shock法」を開発し，Web上で公開している[4,5]。「CARVER＋Shock法」とは，Criticality（危険性），Accessibility（アクセス容易性），Recuperability（回復容易性），Vulnerability（脆弱性），Effect（影響），Recognizability（認識容易性）の6つの特性とその衝撃度から名付けられたものである。しかし，「CARVER＋Shock法」による評価を実施するには，多くの専門家の協力が必要となり，それに伴う費用も高額となることから，中小零細規模の食品企業が多い日本にその評価手法を適応することは極めて困難と考えられた。

我々は，2005年度から，厚生労働科学研究として，「食品によるバイオテロの危険性に関する研究（研究代表者：今村知明奈良県立医科大学教授）」の研究班を設置し，海外の食品防御に対する取り組みを調査するとともに，日本の食品工場の脆弱性を評価し，具体的な食品防御対策を検討してきた[6,7]。具体的には，米国の取り組み等を参考に，食品企業が悪意を持った食品への汚染を防御するための対策（食品防御対策）の必要性に気づき，必要な対策を検討する上で参考となるように，「食品工場における人為的な食品汚染防止に関するチェックリスト（以下「食品工場用チェックリスト」）」や，「食品に係る物流施設における人為的な食品汚染防止に関するチェックリスト（以下「物流施設用チェックリスト」）」をすでに作成している[6,8,9]。しかし，約100項目からなるこれらのチェックリストを用いて食品工場等の脆弱性を評価する場合には，一定の知識と時間が必要となる。さらに，チェックリストに挙げられたすべての対策を実施するにも，多額の費用がかかるなどの課題があった。そのため，日本の食品企業に食品防御対策を普及させるために，チェックリストに挙げられた対策に優先順位をつけ，食品企業が利用しやすい簡便なガイドライン等の作成が必要と考えられた。

こうした背景を踏まえ，すでに作成されている食品工場用チェックリスト[8]から，費用対効果を考慮した「対策推奨度」を整理するとともに，その推奨度を基に「食品防御対策ガイドライン（食品製造工場向け）（以下「ガイドライン」という」やその解説を作成した[10,11]。さらに，食品企業が具体的に食品防御対策を検討するために，食品事業者になじみの深い「総合衛生管理製造過程承認制度実施要領（日本版HACCP）（以下「日本版HACCP」という）」[1]とチェックリストや作成したガイドラインを比較し，食品防御の観点から必要と考えられる対策を検討し，「食品防御の観点を取り入れた場合の総合衛生管理製造過程承認制度実施要領（日本版HACCP）［別表第1承認基準］における留意事項（以下「HACCPの留意事項」という）[12]としてまとめた。

Ⅱ 方　　法

1. チェックリスト項目別の費用対効果の測定と対策推奨度の整理

食品工場用チェックリスト[8]は「組織マネジメント」（21項目），「人的要素（従業員）」（19項目），「人的要素（部外者）」（5項目），「施設管理」（22項目），「経営運営」（27項目）の5分野，計94項目から構成される。食品工場用チェックリストに列挙された対策の中から，費用対効果の高い対策を抽出するため，項目別に効果の大きさと必要な費用の多さからそれぞれ得点化を行い，費用対効果を推定した。さらに，その結果を用いてチェックリスト項目の対策推奨度を整理した。

1)　費用対効果の測定

(1)　費用の設定

食品工場の広さや構造，立地条件，取り扱っている食品等の特性により食品防御対策の効果や費用も異なる。また，その費用には，単価情報や積算方法が含まれることから，公開しないことを条件に，文献7の研究班員（以下，「研究班員」）が，複数の専門業者の協力を得て費用に関する聞き取り調査を行い，以下の分類で得点化した。

①ハード対策（施設整備による対策）

新たな設備の設置費用や維持管理費用等を調査し，初期コスト（年換算）と年間運用コストの凡その金額を算出し，得点化した。

金額の得点化は，極めて高額（5点），高額（4点），やや低額（3点），低額（2点）とした。

②ソフト対策（従業員等による点検作業や作業方法の見直しによる対策）

- 新たな対策の導入による新規雇用や外注のコスト
  継続的なコスト；4点
  短期的なコスト；2点
- 内部対策の実施に伴う業務量の増加
  継続的な増加；3点
  短期的な増加；1点

(2)　効果の設定

チェックリストに挙げられた対策の実施による効果を以下のように分類し，効果の大きい対策を高得点とした。

①社会的要請として最低限行っておくべきと考えられる対策（6点）

②犯行実施の抑止への寄与；直接的（5点）/間接的（4点）
③被害の最小化への寄与；直接的（3点）/間接的（2点）
④安心・信頼の向上に寄与（1点）

2）　チェックリスト項目の対策推奨度の整理

各対策による効果の総得点から，費用の総得点を引き，その大小により推奨度を整理した。ソフト対策では9～11点，ハード対策では7～8点を推奨度A（最も高い）とし，ソフト対策では6～8点，ハード対策では5～6点を推奨度B，それ以外を推奨度C（最も低い）とした。さらに，各種専門家から構成される研究班員による専門家判断（エキスパートジャッジ）を行い，優先度を判断した。

2.　ガイドライン（案）の作成と食品工場への聞き取り調査

食品企業が効率的に食品防御対策を実施できることを目的に，推奨度A，Bとして抽出された防御対策を基に，「ソフト対策」，「ハード対策」に分けて，「最も推奨される対策」，「実施が望まれる対策」を列挙し「ガイドライン（案）」を試作した。

試作したガイドライン(案)を基に，研究班員が，乳製品・調味料・パン・食肉加工品の4か所の食品工場を対象に，聞き取り調査を行った。

具体的には，ガイドライン（案）に示された，優先度の高い対策である人的要素（従業員等）や施設管理，経営運営等の食品防御対策の実施状況を確認した。また，ガイドライン（案）に示された食品防御対策と業務の効率性確保における課題，対策を実施する上で障害となる要因だけでなく，食品防御に対する意識や，食品工場を運営する上で留意している点なども調査した。

これらの聞き取り調査の結果を踏まえて，再度，研究班員による検討を行い，ガイドライン最終案を作成した。

3.　HACCPの留意事項の検討

日本で広く使用されている食品の衛生規範である「日本版HACCP［別表第1承認基準］」には，食品防御の考え方は含まれていないが，承認基準として，製造又は加工の工程に関する文書，施設の図面，危害の発生を防止するための措置，改善措置の方法，記録，管理体制等に関する基準が定められている。このため，日本の食品工場で食品防御の考え方を普及させ，具体的な対策が実施できるようにするために，日本版HACCPと食品工場用チェックリストや作成したガイドラインを比較し，食品衛生管理と併せて食品防御対策を検討する場合に必要となる考え方を検討し，「HACCPの留意事項」として整理した。

4.　倫理面への配慮

本研究において，特定の研究対象者は存在せず，倫理面への配慮は不要である。なお，本研究で得られた成果はすべて厚生労働省に報告しているが，一部テロ実行の企てに悪用される恐れのある情報・知識については，非公開としている。

Ⅲ　結　　果

1.　費用対効果からみた推奨される対策とガイドライン（案）の試作

費用は平均3.0点（最高9点，最低1点），効果は平均8.4点（最高15点，最低1点）であった。

効果の点数が最も高い対策は，施設管理対策の一つである「敷地内における警備員の巡回やビデオ監視」であったが，費用も同様に最も高い点数を示した。逆に費用の点数が低い対策としては，人的要素(従業員等)に含まれる適切な従業員管理の徹底や，工場内のアクセス制限，経営運営や施設管理対策である商品や試薬等の管理基準等の作成であった。

推奨度Aとして，ソフト対策12項目，ハード対策3項目，推奨度Bとして，ソフト対策42項目，ハード対策8項目が抽出された。抽出された推奨度に基づき，「ソフト対策」，「ハード対策」に分けて試作されたガイドライン（案）に示された対策を表1に示す。

2.　食品工場への聞き取り調査の結果

推奨度を踏まえて試作したガイドライン（案）を基に4か所の食品工場に対して聞き取り調査を行った。

組織マネジメントに関しては，食品工場からは，従業員に対する食品防御に関する監督・教育は，逆に従業員に好ましくない情報を与えてしまうこと，会社が従業員を信頼していないというメッセージとして受け取られてしまう可能性があること等の懸念が示された。その一方で，多くの工場では，風通しの良い職場環境づくりや，メンタルヘルス対策等はすでに実施されていた。

人的要素（従業員等）に関しては，私物，医薬品等の持ち込みは，多くの食品工場では制限しているが，逐一のチェックはなされていなかった。従業員の職制・職能別の工場内施設別（工程別）のアクセス権は，業務の効率性を阻害しない様に留意する必要があるのと意見が聞かれるとともに，アクセス権の設定は，施設面の対策に含まれるとの意見が多く聞かれた。

人的要素（部外者）に関しては，部外からの来訪者の荷物（車輌への積載品も含む）の検査が行われ

表1　抽出された推奨度に基づき，「ソフト対策」，「ハード対策」に分けて試作されたガイドライン（案）に示された対策

最も推奨される対策	実施が望まれる対策
【ソフト対策】	
○組織マネジメント	
• 人為的な食品汚染の脅威や，実際の発生時の対応策にかかる計画の策定（A1） • 回収された製品の取扱い方法と廃棄方法の策定（A2）	• 「人為的な食品汚染」に関する観点を含んだ食品汚染対策の手続きや，それに必要となる安全評価の実施（B1） • 人為的な食品汚染を行わせない従業員の監督体制の構築（B2） • 人為的な食品汚染行為に脆弱な箇所の安全性を日常的な確認（B3） • 製品回収の基準の策定（B4） • 警備保障会社職員（もしくは社内の警備担当者）の業務内容の確認・報告（B5）
○人的要素（従業員等）	
• 従業員の採用・勤務 • 従業員の異動・退職時などの制服や名札，IDバッジの回収（A3），鍵（キーカード）の回収（A4）。 • 職能・時間に応じた施設内アクセスエリアの制限（A5）と，すべてのエリアに無制限にアクセス可能な従業員の認識・特定（A6） • 従業員の異常な健康状態や欠勤の把握（A7）	• 工場内へ持ち込む私物の制限（B6） • 工場内への医薬品の持ち込み制限（B7） • 私物の持込みエリアの制限（B8） • 人為的な食品汚染行為等やその脅威に対する内容を含んだ職員訓練プログラムの実施（B9） • 人為的な食品汚染に対する予防措置の重要性に関する定期的な意識喚起（B10）
○人的要素（部外者）	
	• 疑わしい・不適切なあるいは通常でない物品や行動，車両，荷物の検査の実施（B11） • 訪問者に対しての社員の同行の義務付け（B12） • 訪問理由の確認（B13） • 訪問者の身元の確認（B14）とその方法（B15） • 訪問者の食品取扱い/保管エリア/ロッカールームへのアクセスの制限（B16）
○施設管理	
• 汚染物質を一時的に留すことができる場所，死角・暗がりになる場所等の洗い出し・安全確認（A8）	• 鍵の管理方法の策定（B17） • 工場内部と外部との結節点の安全確認（B18）と施錠（B19） • 非稼動時の安全確認（B20） • 立入禁止区域への入口の安全確認（B21） • 研究施設（検査・試験室）へのアクセス制限（B22） • 研究材料（検査薬・試験薬）の保管場所および保管方法の決定（B23）およびアクセス制限（B24） • 試薬の紛失等に関する事態の調査・通報の体制の構築（B25） • 不要な試薬の安全な廃棄（B26） • 有毒物質等の在庫量（B27）とその定期的な確認方法（B28）・保管方法（B29），保管場所へのアクセス制限（B30） • 殺虫剤の選定基準（B31）と保管方法の策定（B32） • 研究材料や有毒物質等の在庫の紛失やその他の事態の発生状況の調査や，発生時の通報体制の構築（B33）

表1　抽出された推奨度に基づき，「ソフト対策」，「ハード対策」に分けて試作されたガイドライン（案）に示された対策（つづき）

最も推奨される対策	実施が望まれる対策
○経営運営	
• 在庫の紛失や増加，その他の事態の調査や通報の体制の構築（A9） • 納入先における最終製品の在庫の紛失や増加，その他の事態の調査や通報の体制の構築（A10） • コンピューター処理制御システムや重要なデータシステムへのアクセス許可者を制限（A11） • 従業員の異動・退職時等におけるコンピューターアクセス権の削除（A12）	• 資材や原材料等の受領前の，納入資材等のラベルや包装の形態の確認（B34） • 納入資材の積み下ろし作業の監視（B35） • 納入製品・数量と，発注製品・数量との整合性の確認（B36） • 納入資材の人為的な食品汚染行為等の徴候・形跡の調査や通報の体制の構築（B37） • （井戸水を利用している場合）井戸水の安全性検査の結果の変化への注意（B38） • 出荷製品の荷受人の把握（B39） • 最終製品に対する苦情（B40）や健康被害情報（B41）が寄せられた場合の調査や通報の体制の構築 • コンピュータのデータ処理に係る履歴の保存（B42）
【ハード対策】	
○人的要素（従業員等）	
• 従業員の職位や特性に応じた明確な識別・認識システムの構築（A1） • 定期的な暗証番号の変更や鍵の取替え（A2）	• 敷地内に存在する者の所在の把握（B1）
○施設管理	
• 敷地内を走行する車両に対する駐車許可証，アクセスキー，通行許可証のいずれかの発行（A3）	• フェンス等による敷地へのアクセス制御（B2） • 敷地内における警備員の巡回やビデオ監視（B3） • 敷地内にある有毒物質等の所在や保管量を把握，監視（B4）
○経営運営	
	• 保管中の納入資材や使用中の資材の監視（B5） • 井戸，給水栓，貯蔵施設の安全性確保（B6） • 井戸水を利用している場合，水，およびその関連施設を塩素殺菌する設備の監視（B7） • 出荷した製品の積荷の位置を常時確認可能な体勢の検討（B8）

（参考文献7より筆者要約）

ていないことや，原材料や資材等の搬入のための運送業者以外にも，比較的頻繁に宅配業者が出入りしていることも判明した。部外からの来訪者への社員の同行については，初めての場合は同行するが，顔馴染みには同行しないことや，身元の確認は，集団での来訪者の場合は代表者のみで，一人ひとりは詳細に確認していないケースがほとんどであった。部外からの来訪者にはグループ会社や委託業者等も含まれるため，一律に社員の同行の有無の線引きは難しいとの指摘があった。

施設管理については，暗証番号の変更や鍵の取替えは，ほとんど行われていない現状が把握された。保管中の有毒物質や納入資材は，出納表等で使用量を管理されていることや，保管場所が使いやすいよう製造現場に近いことが一般的であった。

経営運営については，原料や資材等の数量が入荷時に増加していた場合，増加分の具体的な特定方法の事例は聞き取ることができなかった。出荷製品の出荷時の荷姿は確認しているが，出荷製品数が当初予定数より予期せず増加した場合，その増加分の特定が困難である現状が把握された。また，大項目名である「経営運営」の意味が難解との意見もあった。

表2　食品防御対策ガイドライン（食品製造工場向け）の概要

食品防御対策ガイドライン（食品製造工場向け）
―意図的な食品汚染防御のための推奨項目―

1.　優先的に実施すべき対策

■組織マネジメント
- 働きやすい職場環境の醸成と，自社および自社製品への愛着や責任感の高揚
- 意図的な汚染が疑われる事態発生時の原因究明や情報公開のための勤務状況や業務内容の把握と，従業員等への意識付け
- 製品の異常の早期発見のための苦情や健康危害情報等の確認，意図的な食品汚染発生時の社内外への報告，製品の回収，保管，廃棄等の手続きの策定

■人的要素（従業員等）
- 採用時の可能な範囲での身元確認，各種証明書や資格等の原本確認
- 異動・退職時等に制服や名札，IDバッジ，鍵（キーカード）の返却，識別・認識システムの構築，新規採用者の認知
- 製造現場内への持ち込み可能品リストの作成と遵守の確認
- 従業員等の異常な言動，出退勤時間の著しい変化等の把握

■人的要素（部外者）
- 訪問者の身元・訪問理由・訪問先等の確認と従業員の同行
- 訪問者の車両のアクセスエリア，荷物の持ち込みエリアの設定
- 工場内を単独行動する訪問者の持ち物の確認，不要物持ち込みへの留意
- 郵便，宅配便の受け入れ先の設定，建屋内への立ち入り，資材・原材料や製品への接近への留意

■施設管理
- 不要物，利用者・所有者が不明な物の定常的な確認
- 食品に直接手を触れることができる工程や従事者が少ない場所等，意図的に有害物質を混入しやすい箇所の把握と，防御対策の検討
- 非稼動時における防犯対策
- 鍵の管理方法の策定，定期的な鍵の取替え・暗証番号の変更等による外部からの侵入防止対策の実施
- 工場内部と外部との結節点の特定と対策の実施
- 工場内の試験材料（検査用試薬・陽性試料等）や有害物質の保管場所の設定，管理・保管方法・在庫量の確認方法等の策定と，在庫品紛失等発生時の通報体制の構築
- 殺虫剤の選定基準および管理・保管方法の策定
- 井戸，貯水，配水施設への侵入防止措置や浄化関連設備へのアクセス管理・監視の実施
- コンピューター処理制御システム等へのアクセス許可者の制限，異動・退職時等のアクセス権解除，データ処理履歴の保存

■入出荷等の管理
- 資材や原材料等のラベルや包装の確認，意図的な食品汚染行為等の兆候・形跡発見時の調査や通報の体制の構築
- 資材や原材料等の納入作業および製品出荷作業の監視
- 納入製品・数量と，発注製品・数量との整合性の確認
- 保管中の在庫の紛失・増加，意図的な食品汚染行為等の兆候・形跡，納入量過不足（紛失や増加）等が判明した際の調査や通報体制の構築
- 納入製品の荷受先の確認方法の共有

2.　可能な範囲での実施が望まれる対策

■組織マネジメント
- 警備・巡回結果の報告内容の明確化

■人的要素（従業員等）
- 敷地内の従業員等の所在の把握

■施設管理
- 敷地内への侵入防止対策
- 警備員の巡回やカメラ等による工場建屋内外，資材や原材料，有害物質，施錠確認等

（文献11より筆者要約）

表3　HACCPにおける食品防御の観点からの留意事項に記載された内容

- 食品防御対策の責任者の選任
- 出入り口，原材料納入口，製品出荷口などの外部との結節点の監視や施錠等の防犯体制
- 部外者との接点の有無や監視状況
- 持ち込み品の検査
- 機械器具の配置による死角
- 従業員の職制に応じた立入可能エリアや，図面へのアクセス制限
- 作業手順や作業標準に従った配置や動線からの逸脱など，作業員の行動のモニタリングや作業員同士の相互監視等による投入行為の抑制
- 人為的な異物投入の可能性の恐れがある工程や原因物質の特定
- 従業員や関連する部外者への食品防御に対する教育の実施
- 従業員の休憩室や，薬品庫・工作室・工務室等異物の保管場所と製造現場との区別やアクセス管理
- 設備や機械器具の保守点検時の工程外の改修の有無の確認
- 殺虫剤等の選定や管理
- 使用水やその設備等の管理
- 不適格品の再利用や廃棄等の取り扱い方法や，回収製品の保管や廃棄方法の策定
- 記録保管時の盗難や部外者への漏出への注意

（文献12より筆者要約）

ガイドラインの構成については，ソフト対策とハード対策に分けることが困難な対策もあることから，優先度で記載すべきとの意見や，ガイドラインのみでは，食品企業が採るべき具体的な対策が分かりづらいとの意見が多く聞かれた。

3.　食品防御対策ガイドライン（食品製造工場向け）の作成について

聞き取り調査の結果を踏まえて，各種専門家から構成される研究班員による検討を行い，ソフト対策とハード対策に分けずに，最終的には，「優先的に実施すべき対策」，「可能な範囲での実施が望まれる対策」の2段階からなる「食品防御対策ガイドライン（食品製造工場向け）」[10]が作成された。

チェックリストやガイドライン（案）では，人的要素（従業員等・部外者）や経営運営に含まれていた対策の内，設備や施設に関係する対策は「施設管理」にまとめるとともに，大項目名の「経営運営」は，最終案では「入出荷等の管理」に改められた。

その結果，ガイドライン最終案には，「優先的に実施すべき対策」としては，組織マネジメント（4項目），人的要素（従業員等）（5項目），人的要素（部外者）（5項目），施設管理（14項目），入出荷等の管理（6項目）の計34項目が，「可能な範囲での実施が望まれる対策」としては，組織マネジメント（1項目），人的要素（従業員等）（1項目），施設管理（4項目）の計6項目が列挙された。

完成したガイドラインの概要を表2に示す。

また，ガイドラインが食品工場の現場における対策を強制するものではなく，「可能な範囲での対策の必要性の気付きを得る」ためのものであるとの趣旨・目的を説明文に明記した。

さらに，ガイドラインのみでは，食品企業が採るべき具体的な対策が分かりづらいとの意見を踏まえて，食品企業が具体的に食品防御対策を検討する上で参考となるようガイドラインの［解説］[11]を作成した。解説には，人為的な食品汚染に対する対応計画の作成，警備担当者からの報告内容，人為的な食品汚染に対する職員訓練プログラム，殺虫剤購入時の選定基準，在庫や最終製品の増加時における対応方法や増加分の特定方法等について，具体的な内容を分かりやすく記載した。

4.　HACCPにおける食品防御の観点からの留意事項

「日本版HACCP」と，食品工場用チェックリストやガイドランと比較した結果，日本版HACCPの承認基準に，食品防御の観点からの留意事項を追記することが，日本の食品企業が食品防御対策をとる上で有用と考えられた。具体的には，製造又は加工の工程に関する文書，施設の図面，危害の発生を防止するための措置，改善措置の方法，記録，管理体制について，それぞれ食品防御の観点からの留意点が追記された。

ガイドラインの参考資料として公表されている「HACCPの留意事項」[12]に記載された内容の概略を表3に示す。

Ⅳ　考　　察

2001年の9.11世界同時多発テロ以降，WHOの

「食品を介するテロの脅威に対するシステムに関するワーキンググループ」の開催や，「食品テロの脅威に対抗するためのWHOへの勧告」，Terrorists Threats to Food（食品テロの脅威への予防と対応のためのガイダンス）の作成，米国での『食品セキュリティ予防措置ガイドライン"食品製造業，加工業および輸送業"編』の作成や，食品テロに対する脆弱性評価手法としての「CARVER＋Shock法」の開発，アジア太平洋経済協力（APEC）や経済協力開発機構（OECD）におけるテロ対策委員会の開催など，世界的に食品テロ対策の重要性が高まっている[1~15]。

その一方，日本では，食品企業の60％は食品テロを想定しておらず，さらにその内の60％は食品テロの可能性は低いと考えているなど，食品テロに対する認識が低いことが指摘されている[16]。我々が国内8か所の代表的な食品関連施設（牛乳，弁当，納豆，清涼飲料，大規模集客施設等工場6か所，物流施設2か所）を対象に試行した"CARVER＋Shock法"による脆弱性評価の結果からも，テロや犯罪行為（人為的な異物混入等）に対する食品工場のセキュリティ対策の実施状況はかなり低く，とくにセキュリティ対策の基本である，現場におけるテロや犯罪行為に対する危険性の認識は，極めて低いものであった[6]。

こうしたことから，日本の食品企業の食品テロに対する認識を高め，具体的な対策を検討することが喫緊の課題となっていた。

我々はすでに，FDAの『食品セキュリティ予防措置ガイドライン"食品製造業，加工業および輸送業"編』を参考に，「組織マネジメント」，「人的要素（従業員等）」，「人的要素（部外者）」，「施設管理」，「経営運営」の5分野，計94項目に渡る「食品工場用チェックリスト」と，「組織マネジメント」，「人的要素（従業員等）」，「人的要素（部外者）」，「施設管理」，「経営運営」の5分野，計98項目からなる「物流施設用チェックリスト」を作成し，食品工場や食品の物流施設での食品防御対策の重要性の気付きを促してきた[6,7]。その結果，これらのチェックリストが，大手スーパーや生協等が納入業者に対して使用を促している実態や，倉庫内で勤務する従業員に対して厳格な持ち込み品検査，X線検査を実施している大規模倉庫を有する大手小売業者があることが研究班会議で報告されている[7]。その一方，中小零細規模の食品企業の多い日本において，米国と同様の脆弱性評価の実施や，チェックリストに列挙された対策を推奨することは食品企業の人的要素や経済的な負担を考慮すると現実的ではなく，食品企業が実施しやすい対策を，優先順位をつけて示すことが必要と考えられた。

このような現状を踏まえて，食品工場用チェックリスト項目の対策推奨度を検討し，それを踏まえた「ガイドライン（案）」を作成し，食品企業へのヒアリングを通じて，その実用性を確認し，その意見を踏まえて，「優先的に実施すべき対策」，「可能な範囲での実施が望まれる対策」の2段階からなる「ガイドライン」が完成した。推奨度を検討したことで，チェックリストで示された100項目近い対策が，ガイドラインでは40項目に集約された。さらに，分かりやすい解説を作成したことで，より具体的な対策の検討に資することが期待できる。

日本の食品企業が行っている食品防御対策としては，侵入者対策や原材料のチェック，輸送時の安全管理，搬出入時の職員の立会い，商品の入出荷の際の3時間内の確認は実施されているが，職員の職種による立ち入り先の制限や，搬入・搬出車の封印，搬入品の抜き取り検査は行われていないと言われている[16]。

中小零細規模が多く，家族経営的な食品企業が多い日本においては，従業員への食品防御に関する教育等を実施する場合には，労使の信頼関係を悪化させない特段の配慮が必要と考えられた。今後，食品防御対策を進めるには，食品企業に馴染みの深いHACCPに食品防御の観点を追加し，具体的な対策を実施することが最も効果的と考えられた。

今回作成されたガイドライン[10]や解説[11]，HACCPの留意事項[12]を参考に，日常的に行っている衛生管理や，衛生教育の一環として，「食品防御の考え方」を取り入れていくことが有用であろう。

V　結　　論

食品企業で食品防御対策を普及させるため，費用対効果を測定し，対策の推奨度を踏まえた，実効性・実用性の高い「ガイドライン」とその解説を作成するとともに，食品事業者になじみの深いHACCPに沿った食品防御の観点から留意事項を示した。

ガイドラインは，食品工場に食品防御対策を強制するものではなく，「可能な範囲での対策の必要性の気付きを得る」ためのものである。ガイドラインとその解説や，「HACCPの留意事項」を併用しながら，多くの食品企業が食品防御対策の必要性や具体的な対策を検討されることが期待される。

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Tentative food defense guidelines for food producers and processors in Japan

Yoshiyuki KANAGAWA[*], Manabu AKAHANE[2*], Tomoaki IMAMURA[2*], Atsushi HASEGAWA[3*], Kentaro YAMAGUCHI[3*], Kazuo ONITAKE[4*], Satoshi TAKAYA[5*] and Shigeki YAMAMOTO[6*,7*]

Key words : food contamination, food defense, food defense checklist for food producers and processors, food defense guidelines, CARVER＋Shock, HACCP

Objectives With increasing global interest in intentional food contamination, expert meetings have been held by the G8, while the U.S. government has proposed policies for preventing food terrorism and intentional contamination. However, Japan has no food defense policy, and some food companies are concerned about an impending terrorism and contamination crisis.

Methods We developed a Food Defense Checklist for Food Producers and Processors and published the details on the website. We also developed tentative Food Defense Guidelines for Food Producers and Processors on the basis of the checklist. In this study, we tested the usability of the guidelines through a hearing survey regarding food plants. We also compared the checklist with the implementation manual for the approval system of Comprehensive Sanitation Management and Production Process (the Japanese equivalent of the HACCP).

Results We organized the comments gleaned from the hearing survey and provided a detailed explanation of the guidelines. As the HACCP has been adopted by Japanese food companies, we included both precautionary measures and the HACCP perspective in the explanation regarding the rapid dissemination of information.

Conclusion The guidelines are useful for Japanese food companies, and it is important to disseminate knowledge on this topic and implement food defense measures.

* Division of Social Medicine, Graduate School of Medicine, The University of Tokyo
2* Department of Public Health, Health Management and Policy, Nara Medical University School of Medicine
3* Mitsubishi Research Institute, Inc.
4* Japanese Consumers' Co-operative Union
5* Japan Food Hygiene Association
6* Division of Biomedical Food Research, National Institute of Health Sciences
7* Current address; Course of Food Science, Department of Fishery, School of Marine Science and Technology, Tokai University

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Association between first airborne cedar pollen level peak and pollinosis symptom onset: a web-based survey

Harumi Bando[a], Hiroaki Sugiura[b]*, Yasushi Ohkusa[c], Manabu Akahane[b], Tomomi Sano[d], Noriko Jojima[a], Nobuhiko Okabe[c] and Tomoaki Imamura[b]

[a]*Faculty of Nursing, Nara Medical University, Kashihara, Japan;* [b]*Department of Public Health, Health Management and Policy, Nara Medical University, Kashihara, Japan;* [c]*National Institute Infectious Diseases, Infectious Disease Surveillance Center, Toyama, Japan;* [d]*Kansai Airport Quarantine Station, Tajiri-Cho, Japan*

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Cedar pollinosis in Japan affects nearly 25 % of Japanese citizens. To develop a treatment for cedar pollinosis, it is necessary to understand the relationship between the time of its occurrence and the amount of airborne cedar pollen. In the spring of 2009, we conducted daily Internet-based epidemiologic surveys, which included 1453 individuals. We examined the relationship between initial date of onset of pollinosis symptoms and daily amount of airborne cedar pollen to which subjects were exposed. Approximately 35.2 % of the subjects experienced the onset of pollinosis during a one-week interval in which the middle day coincided with the peak pollen count. The odds ratio for this one-week time interval was 4.03 (95 % confidence interval: 3.34–4.86). The predicted date of the cedar pollen peak can be used to determine the appropriate date for initiation of self-medication with anti-allergy drugs and thus avoid development of sustained and severe pollinosis.

Keywords: seasonal allergic rhinitis; web-based survey; population surveillance; pollinosis; cedar

Introduction

Pollinosis involving immunoglobulin E (IgE)-mediated immediate-type hypersensitivity is an important issue in many countries because of the high rates of morbidity associated with the condition (D'Amato et al. 2007). One meta-analysis revealed that pollinosis has a morbidity of 24.5 % in the general population in Japanese urban cities (Kaneko et al. 2005). However, the morbidity is increasing along with environmental changes, which increase the severity of pollinosis. The social and public health impacts of the condition are highly significant because of the reduction in productivity caused by prolonged symptoms, which can persist for > 2 months (Crystal-Peters et al. 2000; Okubo et al. 2005).

In Japan, *Cryptomeria japonica* (Japanese cedar) is a major representative pollen allergen. This species was planted in large numbers after 1945 because of the increased demand for timber following World War II. Cedar pollen begins to form in July and is almost fully developed by November when the cedar tree enters a dormant state. Cedars awaken from their dormancy and start to flower in early February (Kawashima &

*Corresponding author. Email: tomomarie@smn.enjoy.ne.jp

Takahashi 1999). The scattering of cedar pollen is determined by conditions appropriate for high levels of flowering as well as by weather conditions that enable the pollen to become airborne (Kawashima et al. 1998). The amount of airborne cedar pollen is affected by several variables, including the number of sunlight hours, wind speed and direction, and humidity (D'Amato et al. 2005). When the season begins, only small amounts of cedar pollen are generated, and these are then dispersed by strong winds. At the peak of flowering, large quantities of pollen become airborne, and when these are dispersed by strong winds they may cause pollen storms. The released cedar pollen floats in the atmosphere for long periods and is dispersed over great distances (Okamoto et al. 2009; Awaya & Murayama 2012). Therefore, the daily amount of airborne cedar pollen fluctuates during the allergy season and is influenced by weather conditions (Takasaki et al. 2009).

Epidemiological surveys of pollinosis are usually conducted using patient questionnaire surveys that show trends, but these surveys cannot clarify prevalence (Okuda 2003). Clinical diagnostic techniques, including IgE assays, can provide definitive diagnoses to support information gleaned from patient symptom surveys (Sakashita et al. 2010). However, total morbidity cannot be determined by surveys involving patients treated at medical facilities, because many patients do not seek medical attention when their symptoms are mild, especially early in the allergy season. Therefore, general population surveys on pollinosis are necessary. Once pollinosis occurs, symptoms persist for the duration of the season (Sasaki et al. 2009). Identification of the initial date of pollinosis is necessary to clarify its characteristics and to take appropriate countermeasures. To this end, daily observations are necessary. The Internet is useful for conducting such daily epidemiological investigations (Sugiura et al. 2010, 2011). The first epidemiological survey using the Internet was published in 1996, and others have followed (Bell & Kahn 1996). A benefit of this method is that both individuals who seek medical care and those who do not can be included (Tilston et al. 2010). Internet surveys of the population with and without allergic rhinitis have been conducted using citizens registered with Internet survey companies (Long 2007; Sharp & Seeto 2010). However, most were cross-sectional surveys conducted after the season onset.

In 2007, we developed a web-based daily symptom surveillance method known as the WDQH or Web-based Daily Questionnaire for Health (Sugiura et al. 2010, 2011). Surveys using the WDQH enable the discovery of infection outbreaks and are used to investigate the effects of environmental factors on health conditions in the population (Sano et al. 2013). In the present study, we conducted a survey on pollinosis using the WDQH. The survey was conducted during the spring, prior to the onset of cedar pollinosis symptoms.

The objectives of this study were to evaluate the feasibility of a web-based epidemiological survey of pollen diseases, to determine the daily morbidity and initial date of pollinosis onset, and to clarify the relationship between pollinosis and the amounts of airborne cedar pollen.

Methods

Survey method

The daily survey was conducted between 1 February 2009 and 30 March 2009, and involved 1453 residents of Tokyo, Japan; the study was approved by the Research Ethical Committee of Nara Medical University (No. 220). The study population comprised individuals and their families who ordered food using the Internet and who

were members of the Japanese Consumers' Co-operative Union (CO-OP). The survey involved the CO-OP because the cooperative is interested in promoting the health of its members. At the time of the study, there were 1 million CO-OP members among Tokyo's population of 12.3 million. The participants were recruited through banner advertisements on the CO-OP home page. Participants were rewarded points equal to 100 yen (1 USD = 89 yen at the time of the survey) as a reward for registering. Written informed consent was obtained from all participants. Although there was no monetary reward for responding to the survey, responders gained access to the survey results via a link on the home page, and a short essay about daily health.

Upon registration, respondents provided their CO-OP registration number as well as the sex and age of themselves and their family members. On the survey dates, the investigators sent an email reminder to each respondent. The subjects were given a maximum of 3 days to fill out the questionnaire for each survey day. The contents of the daily surveys involved "yes" and "no" questions asked of each family member regarding 19 symptoms or signs characteristic of infections and allergies (Sugiura et al. 2011).

The study also looked into the medical conditions of all members of families with the representative of each family answering questions on the home page.

In the present study, we analyzed the data acquired for the following five symptoms: runny nose, itchy eyes, sneezing, slight fever, and high fever. Pollinosis symptoms were defined as the simultaneous presence of rhinitis and conjunctivitis in the absence of both slight and high fevers to rule out infectious disease.

To simplify the current survey, respondents were asked to report the presence or absence of pollinosis symptoms, but not their severity. This is because our study was not specific for pollinosis and included questions relating to other infections and allergies; the questions were simplified for ease of daily input.

Data regarding cedar pollen abundance are publicly available on the Internet. We accessed the pollen observation system of the Tokyo Metropolitan Government (TMIPH) and obtained data on daily 24-h airborne cedar pollen levels at Suginami-ku – an urban area, the central area where the subjects lived – from 1 February 2009 to 30 March 2009. The daily amount of airborne cedar pollen is calculated hourly by measuring the pollen-specific fluorescence in 1 m^3 of air obtained using an aspiration pump (KP-1500, Kowa Inc., Nagoya, Japan), which is set up at a height of 12 meters above the ground. This result is reported in real time.

Data analysis

The daily incidences of runny noses, sneezing, and itchy eyes were calculated, and the data were plotted on an epidemiological curve on which the *X*-axis represented the date and the *Y*-axis the number of cases. All pollinosis symptoms were plotted on the same graph and compared with the amounts of airborne cedar pollen. We followed each individual during the entire period, and the initial date of pollinosis symptom onset was identified. The daily number of people experiencing the initial onset of pollinosis symptoms was also calculated.

The odds ratio (OR) of the χ^2 test of pollinosis symptoms was determined before and after the date on which the maximum level of airborne cedar pollen was noted to evaluate the risk of the first pollen exposure. In addition, binary logistic regression analyses were performed to confirm the increases in the initial onset of pollinosis symptoms during a one-week interval with the middle day coinciding with the peak amount of airborne cedar pollen. To correct for inter-subject correlations in the daily survey (among

the same subjects during the study period), a generalized estimating equation method was used. For these analyses, the presence or absence of the initial onset of pollinosis symptoms was designated as the dependent variable, and the independent variable was defined as the one-week interval in which the middle day coincided with the peak amount of airborne cedar pollen. In addition, to adjust for confounding factors, sex and age were included as independent variables. The statistical analyses were performed using SPSS version 19.0 (SPSS, Chicago, IL, USA).

Results

A total of 1453 individuals were enrolled in the survey, which represents an excellent participation rate (96 %) given the number of initial responders exhibiting interest. Over 58 investigation days, the average daily response rate was 40.1 % ± 5.0 %.

The time-course analysis of the daily airborne cedar pollen concentrations revealed a clear relationship between the peak incidence and the severity of allergic responses (Figure 1). The pollen count stood at 34 m^3 day on 1 February, the day when the study began. No recognizable correlation existed between prevalence and the pollen count

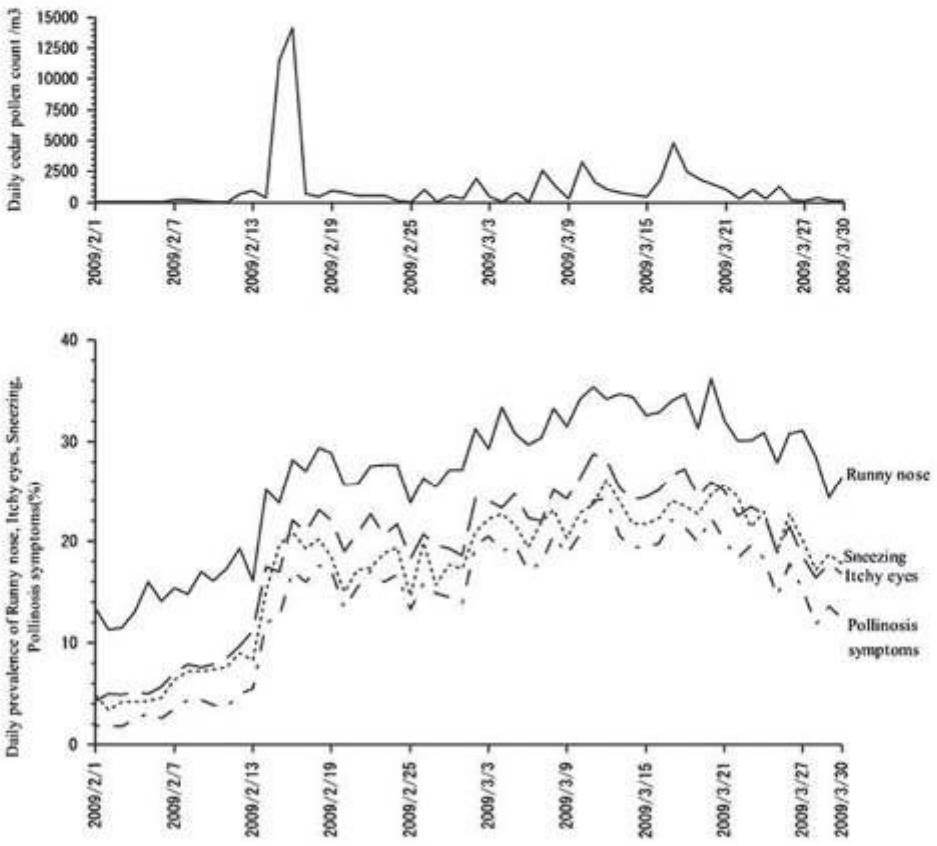

Figure 1. Daily prevalence of patients with individual pollinosis symptoms and daily cedar pollen count.
Notes: Pollinosis was defined as rhinitis together with conjunctivitis in the absence of fever.

over the entire period. The first peak in airborne cedar pollen levels was associated with a dramatic increase in the percentage of subjects reporting all four parameters. We considered a correlation between pollen peaks and subsequent symptoms. The Pearson product-moment correlation coefficient had a value of 0.518 ($p < 0.001$), showing a weak positive correlation.

The percentage of affected subjects remained elevated until the second peak in airborne cedar pollen levels, which was detected during the third week of March. Following the second peak in cedar pollen levels, the symptoms started to subside and continued to do so until the end of the survey period. These data show that allergic reactions were initiated by the first peak in cedar pollen levels and persisted throughout the entire season, even when the cedar pollen levels returned to near the baseline levels.

The number of persons reporting the initial onset of pollinosis symptoms gradually increased and reached a maximum on 16 February, coinciding with the maximum amount of airborne cedar pollen. A cumulative frequency distribution showed that on 12 February, four days before the airborne cedar pollen peak, 21.2 % of the subjects reported the onset of pollinosis symptoms. During the first week (13–19 February), which included the maximum amount of airborne cedar pollen on 16 February, 35.2 % of the patients reported the initial onset of pollinosis symptoms. The cumulative number of persons with an initial onset of pollinosis symptoms by 19 February, three days after the airborne cedar pollen peak, was 56.4 % (Figure 2).

The OR of the χ^2 test for pollinosis symptoms before and after the date of the maximum amount of airborne cedar pollen was 4.66 (95 % confidence interval, 4.22–5.16). A binary logistic regression, which was performed using a generalized estimating equation method, revealed that the OR during the first week of the initial maximum pollen peak vs. the other days, adjusted for sex and age, was 4.03 (95 % CI, 3.34–4.86). Women were more sensitive to pollen levels than men, and the most sensitive group included those between the ages of 20 and 40 years (Table 1).

Discussion

Our findings confirm the feasibility of using a web-based epidemiologic survey of pollen-related conditions to determine the relationship between peak pollen levels and allergic responses. The first peak in the airborne cedar pollen level was associated with a dramatic increase in the initial onset of pollinosis symptoms. However, we clearly showed the persistence of symptoms after pollen levels returned to close to the baseline, and no recognizable correlation existed between prevalence and the pollen count over the entire period. This is a pattern peculiar to Japanese cedar pollinosis, in contrast to European hay fever (Berger et al. 2013).

The subjects resided in densely populated areas of Tokyo. However, Japanese cedar pollen travels even from a remote plantation 100 km away and differs greatly from plant allergens in other countries in that large amounts of it affect patients when blown in by strong winds during blooming in the spring. The quantity defined as "extremely high" is approximately 1000/m^3. A pollen count of 14 times this value was observed in this investigation on the day with the highest count.

We clearly showed that once the subjects had a response to the initial peak in pollen release, they reported symptoms of pollinosis until the end of the season. Thus, the allergic reactions were primed by the first surge in airborne cedar pollen levels and remained elevated for weeks before slowly declining at the end of the season. The large amounts of pollen initially observed caused prevalence to spike at first and then increase

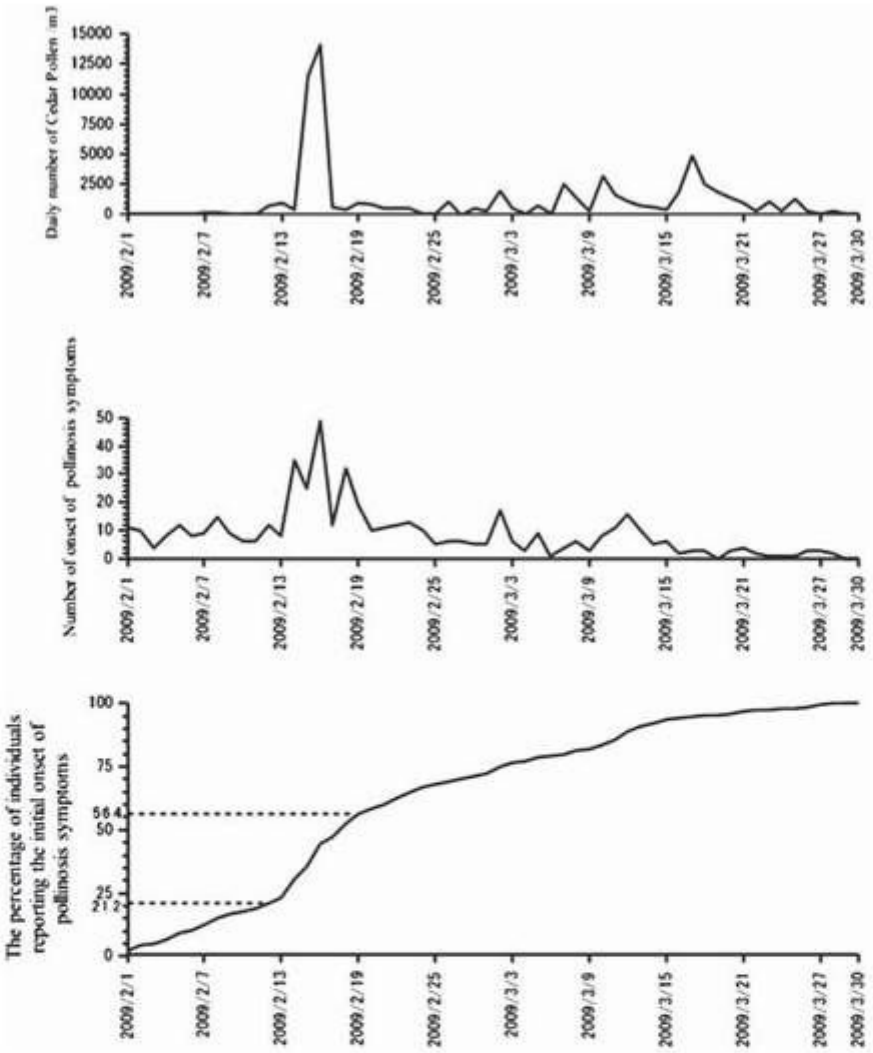

Figure 2. Daily percentage of individuals reporting the initial onset of pollinosis symptoms and the amount of airborne cedar count.

at a slower pace despite a decline in the pollen count. Furthermore, we revealed that there are two phases in the relationship between the pollen count and prevalence. The first is the priming phase associated with the large amounts of pollen initially observed. The logistic regression analysis showed that the initial airborne peak in cedar pollen levels influenced the number of subjects experiencing the incidence of pollinosis. Most subjects who were susceptible to developing severe pollinosis in the Tokyo area were affected by this first peak in airborne cedar pollen levels. The second phase is a period after the initial blip in the pollen count disappears. A reanalysis conducted under the conditions after the initial peak in the pollen count disappeared revealed the existence of a positive correlation between the pollen count and the number of individuals who developed pollinosis symptoms. The second phase, despite a lower daily pollen count, saw a higher prevalence than the first phase. After pollen has dispersed and been scattered in large quantities, it remains in the trees for a few days and can become a source

Table 1. Results from the two-term logistic regression analyses: comparison of the first week with the initial maximum cedar pollen peak and the rest of the pollen season.

	Odds		95 % CI	
	Number	Ratio	Lower limit	Upper limit
One week of the initial maximum cedar pollen peak vs. the subsequent pollen season		4.03	3.34	4.86
≥ 60 years	73	1.99	1.08	3.66
≥ 40 to < 60 years	474	2.48	1.54	3.99
≥ 20 to < 40 years	399	2.67	1.65	4.33
≥ 15 to < 20 years	105	2.1	1.24	3.58
≥ 10 to < 15 years	138	2.3	1.36	3.9
≥ 5 to < 10 years	128	1.88	1.08	3.27
Reference: < 5 years	136			
Women vs. men		1.26	1.08	1.47

for later scattering. In addition, because individuals are in a sensitive state, they are primed for symptomatic reactions, even if the amount of pollen does not increase markedly. This explains the lack of a correlation between prevalence and the pollen count over the entire period. These findings are new and have never been reported in previous research.

Prophylactic administration of anti-allergy drugs before the initial peak in airborne cedar pollen levels would be beneficial for individuals who normally experience seasonal pollen allergies. Therefore, the identification of the initial peak in the airborne cedar pollen level is of paramount importance.

The population in the current study was already symptomatic when the onset of pollinosis was detected at the beginning of the season. However, the present study demonstrated that most subjects reported the onset of pollinosis when a large amount of pollen was present. During the days before and after 16 February (13–19 February), when the level of airborne cedar pollen reached its maximum value, 35.2 % of the subjects reported the initial onset of pollinosis symptoms. This finding indicates that the initial large amount of airborne cedar pollen caused seasonal pollinosis in many citizens. By 19 February (3 days after the maximum level of airborne cedar pollen), 56 % of the subjects (the cumulative total number of subjects from the initial date) had reported the onset of pollinosis symptoms. Another study on the relationship between cedar pollinosis onset and cedar pollen count in patients seeking care at medical facilities found that there was a distinct initial peak of onset (Dejima et al. 1992). Because that study was a patient-based study, only seriously ill individuals were included; however, even small amounts of pollen scattering were believed to induce reactions.

Medek et al. (2012) reported a daily symptom investigation of 42 hay fever patients and the pollen relationship with the daily climate using a web-based survey. Their study clarified the daily nasal rhinoconjunctivitis symptoms of patients and the pollen load via a web investigation. Moreover, the present study demonstrated that web-based surveys can be used to determine these patterns in the general population, and such surveys are presumably easier and faster to use and administer than paper-based questionnaires; they may also help to determine the initial onset of symptoms. Another advantage of using an Internet survey is that epidemiological data can be gathered early in the season to

develop better preventive measures. The fast-growing social and economic burden of pollinosis in Japan calls for an improvement in preventive measures to better inform the population of the onset of airborne cedar pollen exposure. Because patients seeking medical attention present with severe symptoms, the present study used an Internet-based survey to ensure that patients with mild symptoms were also included in the population study. This approach allowed us to identify the onset of mild symptoms within the allergy season, and to identify the citizens most at risk of developing severe and persistent pollinosis symptoms.

A logistic regression by age group showed that the age range included subjects between 20 and 40 years of age who represented a highly sensitive population in this Tokyo-based investigation. Young children are normally very susceptible to allergies, and this is a major concern for clinicians. A breakdown of the data analysis of those < 20 years of age (data divided into 5–10, 10–15, and 15–20 year age groups) revealed that pollen symptoms were also present in individuals aged 5–10 years. This supports previous data published after an investigation of allergies among primary school-aged children in Tokyo (Futamura et al. 2011).

An Internet survey has several advantages over conventional paper surveys. Generally, the amount of data acquired is greater in epidemiological surveys performed using the Internet than in conventional paper surveys (Schleyer & Forrest 2000; Ekman et al. 2006). Another advantage is the inclusion of subjects with mild and early symptoms who do not normally seek care at medical facilities (Bell & Kahn 1996). Of note, however, is that baseline information is not available for these studies. In our present survey, there was a high response rate, the symptoms of pollinosis were reported every day, and sufficient data were available for reliable statistical analyses. Regarding the response rate and sampling, the average online survey response rate was 39.6 % according to a meta-analysis performed of 68 surveys. We would consider therefore that the survey had a satisfactory response rate for an online survey conducted daily (Cook et al. 2000).

A limitation of this study was that the analysis was only based on the data from 2009. Therefore, similar studies should be conducted over several seasons. Another limitation was that the number of patients who used oral anti-allergic drugs might have been underestimated. Therefore, in future studies, questions regarding the use of anti-allergic drugs may need to be included. This study discusses incidence based solely on reports on cedar pollen-related symptoms. Although confirmation through a blood test is essential to avoid a false-positive result, we could not perform blood tests in conjunction with an epidemiological study because of the Personal Information Protection Law (Okamoto et al. 2009) in Japan. Despite this limitation, our web-based survey proved to be suitable for documenting trends associated with cedar pollinosis in Tokyo.

In conclusion, aiming to identify the initial day of onset of pollinosis, this Internet survey clarified the statistical significance of airborne pollen quantity and pollinosis symptoms. The first peak in the airborne cedar pollen level was associated with a dramatic increase in the initial onset of pollinosis symptoms. This finding can be used to predict the appropriate date for the initiation of self-medication with anti-allergy drugs and thus avoid the development of sustained and severe pollinosis (Gotoh et al. 2011).

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